Effect of Integrated Yoga as an Adjuvant Therapy to Standard Care in Pulmonary Tuberculosis- A Randomized Control Trial

A Thesis submitted for the award of

DOCTOR OF PHILOSOPHY

IN

YOGA

degree based on the research carried out in the Department of

Integrative Medicine

under the Faculty of Allied Health and Basic Sciences

by

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Date:15.05.2024 Ph.D. Scholar

LIST OF ABBREVIATIONS

S.NO	Abbreviations	Full forms
01	PTB	Pulmonary Tuberculosis
02	TB	Tuberculosis
03	MDR-TB	Multidrug-Resistant Tuberculosis
04	XDR-TB	Extensively Drug-Resistant Tuberculosis
05	RNTCP	Revised National Tuberculosis Control Programme
06	WHO	World Health Organization
07	NTEP	National Tuberculosis Elimination Programme
08	AIDS/HIV	Acquired Immuno-Deficiency Syndrome/ Human Immunodeficiency Virus
09	QOL	Quality of Life
10	LTBI	Latent TB Infection
11	NAAT	Nucleic Acid Amplification Tests
12	LPA	Line Probe Assays
13	CXR	Chest X-ray
14	CT	Computed Tomography
15	BAL	Broncho-Alveolar Lavage
16	INH	Isoniazid
17	RIF	Rifampicin
18	PZA	Pyrazinamide
19	EMB	Ethambutol
20	DOT	Directly Observed Therapy
21	HRQOL	Health Related Quality of Life

22	CAM	Complementary and Alternative Medicine
23	MTB	Mycobacterium Tuberculosis
24	HDRS	Hamilton Depression Rating Scale
25	PHQ	Patient Health Questionnaire
26	GAD	Generalized Anxiety Disorder
27	HPA	Hypothalamic-Pituitary-Adrenal
28	PFT	Pulmonary Function Tests
29	FEV1	Forced Expiratory Volume in 1 second
30	FVC	Forced Vital Capacity
31	SNOSE	Sequentially Numbered, Opaque, Sealed Envelopes
32	NSP	National Strategic Plan
33	DDG-TB	Deputy Director General - TB
34	IRL	Intermediate Reference Laboratories
35	C&DST	Culture and Drug Susceptibility Testing
36	CTD	Central TB Division
37	NIC	National Informatics Centre
38	BMWM	Biomedical Waste Management
39	MoHFW	Ministry of Health and Family Welfare
40	RLJH& RC	RL Jalappa Hospital and Research Centre
41	SD	Standard Deviation
42	RCT	Randomized Controlled Trial
43	PPE	Personal Protective Equipment

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ABSTRACT

Background:

Pulmonary tuberculosis (PTB) is highly infectious, predominantly affects the lungs and its functions, and is often associated with psychological comorbidities, including depression and poor quality of life. Yoga therapy emerged as a holistic mind-body practice and has positively impacted physical and mental health outcomes.

Objectives:

The objective of the present study was to evaluate the impact of integrated Yoga on Pulmonary Function tests, Depression, and Health-Related Quality of Life (QOL) in patients with PTB.

Methodology:

It was a Randomized control trial study design. The study has screened 826 PTB patients. Seventy-two newly diagnosed PTB patients were selected based on inclusion and exclusion criteria from a tertiary care hospital. They were randomly assigned to the Yoga group (n = 36) and Control group (n = 36) using a sequentially, numbered, opaque, sealed, envelope (SNOSE) technique. The control group patients were treated with standard care (Anti-tuberculosis treatment (ATT)). The Yoga group patients were intervened with a validated Yoga module as an adjuvant to standard care. The Yoga module consisted of Yogic postures, Yogic breathing, and relaxation techniques, which lasted 45 minutes. Pulmonary Function tests were assessed using Spirometry, Health-Related Quality of Life was evaluated using the World Health Organisation Quality of Life BREF questionnaire (WHOQOL-BREF) and Depression was assessed using the Hamilton Depression Rating Scale (HDRS) for all the patients at baseline and post-intervention (after 8 weeks).

Results:

Data followed the normality, so data were analyzed using parametric tests between and within groups. Within-group analysis showed a significant improvement in pulmonary functions

scores FEV1, FVC, and % FEV1/FVC scores compared to baseline to 8th week, which were statistically significant with $p < 0.0013$, $p < 0.001$ and $p < 0.001$ effect size 0.29, 0.45 and 0.91. Reduction in depressive symptoms in both the Control ($p < 0.001$; ES = 1.59) and Yoga ($p < 0.001$; ES = 3.61) groups were observed. Similarly, within-group comparison of Health-Related QOL scores showed significant improvement i.e., physical (p is less than 0.001), psychological (p is less than 0.001), and social (p is less than 0.001) except environmental domain is not significant with $p = 0.893$. However, the effect size (ES) was higher in the Yoga group compared to the control.

Between-group comparison at the baseline there is insignificant values of Pulmonary Function Tests (FEV1 < 0.9551, FVC < 0.9641 and %FEV1/FVC < 0.8969), Health-Related Quality of Life scores (Physical Domain<0.633, Psychological Domain<0.699, Social Domain<0.653 and Environmental Domain <0.656) and Depression scores (<0.34) and after 8 weeks of intervention there is a significant improvement. Yoga group exhibited a significant reduction in depressive symptoms (<0.001), enhanced Health-Related Quality of Life scores (Physical Domain<0.001, Psychological Domain<0.002, Social Domain<0.001 and except Environmental Domain <0.283) and Depression scores (<0.34) and improvement in Pulmonary Function Tests (FEV1 < 0.001, FVC < 0.001 and %FEV1/FVC < 0.01) values compared to the Control group for between-group analysis.

Conclusion:

The research evidence endorses the use of Yoga as an adjuvant treatment for patients undergoing the National Tuberculosis Elimination Program (NTEP) in patients with pulmonary tuberculosis (PTB) to enhance their Pulmonary Function values, quality of life (QoL) scores, and reduced depression symptoms. Yoga may be incorporated into NTEP to improve physical and mental health. The present study is single-centred with short-term intervention hence multi-centric studies with long-term, robust design interventions are warranted.

Keywords: Tuberculosis; Yoga; Pulmonary Function Tests; Quality of Life; Depression; Mental Health; Complementary Therapy; Respiratory Disease; Communicable Disorder.

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Chapter-1: Introduction

1.1 Background

Tuberculosis (TB) is the most contagious and most common infectious disease in the world. (1) Tuberculosis has been a significant public health concern for centuries, with evidence of the disease dating back to ancient civilizations. Mycobacterium tuberculosis (MTB) bacteria causes tuberculosis. MTB has ancient origins of living for 70,000 years of history. It was historically called consumption disease due to weight loss. (2) However, modern scientific understanding and research on TB have advanced considerably.

In the late 19th and early 20th centuries, the discovery of the tubercle bacillus by Robert Koch in 1882 significant crucial turning point in TB research. (2) This breakthrough laid the foundation for understanding the microbial cause of the disease, enabling considerable progress in diagnosis, treatment, and prevention.

Throughout the 20th century, TB research focused on developing effective treatments, particularly with the discovery and widespread use of antibiotics such as streptomycin, isoniazid, rifampicin, and ethambutol. (3,4) These drugs revolutionized TB therapy, leading to significant reductions in mortality and transmission rates.

However, the emergence of drug-resistant strains, particularly multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), presented new challenges and spurred renewed research efforts. (5) Scientists have been investigating new treatment regimens, diagnostic techniques, and vaccines to combat these resistant strains and improve TB control efforts.

In recent years, research has also focused on addressing TB in specific populations, such as those co-infected with HIV/AIDS, as well as improving TB surveillance and control strategies globally. Additionally, there has been a growing emphasis on understanding the socio-economic factors contributing to TB transmission and implementing interventions to address them effectively. (6,7)

Advancements in molecular biology, genomics, and computational modeling have further enhanced our understanding of TB pathogenesis, drug resistance mechanisms, and host-pathogen interactions. These advances offer promising avenues for the development of novel interventions and strategies to achieve the goal of ending the TB epidemic worldwide.

In Tuberculosis most of the infections that do not show any symptoms are called latent Tuberculosis. But only 10% of latent tuberculosis progresses into active Tuberculosis (TB).

(8,9) If a tuberculosis infection becomes active, then most commonly involves the lungs called Pulmonary Tuberculosis (in about 90% of cases) but also other parts of the body called Extra Pulmonary Tuberculosis. Most of the Pulmonary Tuberculosis (PTB) will affect the upper lobes of the lung compared with the lower lobes. (10)

1.2 Etymology

Tubercle: The word "tuberculosis" is derived from the Latin word "tuberculum," which means "a small swelling or protuberance." This term was originally used to describe the characteristic small nodules or lesions that form in the lungs and other tissues during the disease.

-osis: The suffix "-osis" in "tuberculosis" is a common suffix in medical terminology that denotes a pathological condition or disease. When combined with "tuberculum," it forms "tuberculosis," referring to the pathological condition characterized by the presence of tubercles.

Historical Context: The term "tuberculosis" came into common usage in the 19th century as the understanding of the disease evolved. Prior to that, tuberculosis was referred to by various names such as "consumption" or "phthisis." The adoption of "tuberculosis" reflected a more precise understanding of the disease process and its pathological features.

Overall, the etymology of "tuberculosis" reflects the historical and medical context in which the term emerged, drawing from Latin roots to describe the characteristic lesions associated with the disease.

The word "pulmonary" originates from the Latin word "pulmo," which means "lung." It is commonly used in medical terminology to refer to anything related to the lungs.

The term "tuberculosis" has its roots in the Latin word "tuberculum," which means "a small swelling or protuberance." It was first coined by the German physician Johann Schönlein in the early 19th century to describe the characteristic tubercles or nodules found in tissues affected by the disease.

Therefore, "pulmonary tuberculosis" combines these two terms to specifically refer to tuberculosis that primarily affects the lungs. It denotes the form of tuberculosis where the bacteria Mycobacterium tuberculosis infects the pulmonary tissue, leading to symptoms such as coughing, chest pain, and difficulty breathing.

1.3 Definition

Medical Definition: Tuberculosis (TB) is a contagious bacterial infection that primarily affects the lungs (pulmonary tuberculosis) but can also affect other parts of the body (extrapulmonary tuberculosis). (11) It is caused by the bacterium Mycobacterium tuberculosis and is spread through the air when an infected person coughs or sneezes. (12)

Public Health Definition: Tuberculosis is a global health concern characterized by its high burden of morbidity and mortality, particularly in low- and middle-income countries. It is considered one of the top infectious disease killers worldwide and poses significant challenges to healthcare systems and public health efforts.

Historical Definition: Tuberculosis has been known throughout history by various names, including "consumption" and "the white plague." It has been a prominent disease for centuries, with records of its impact dating back to ancient civilizations. Historically, TB was often associated with poverty, overcrowding, and unsanitary living conditions.

Social Definition: Tuberculosis carries social significance due to its impact on affected individuals, families, and communities. It can lead to stigma and discrimination, particularly in societies where misconceptions about the disease persist. Addressing the social aspects of TB, including access to healthcare, education, and socioeconomic factors, is crucial for effective control and prevention efforts.

1.4 Prevalence

1.4.1 Global Prevalence

Even with notable progress in medical science and healthcare, tuberculosis continues to pose a significant global health challenge. As per the World Health Organization (WHO), TB ranks among the top ten causes of mortality globally and stands as the foremost cause of death resulting from a single infectious agent. The prevalence of TB is notably higher in low- and middle-income nations, where issues like poverty, malnutrition, crowded living conditions, and restricted healthcare access play a significant role in its transmission. (13–15)

According to WHO Report 2023, 10.6 million people fell ill with this curable and preventable disease in the year 2022, equivalent to 133 incident cases per 100,000 population. (16)

Among all incident TB cases, 6.3% were among people living with HIV.

The rise in TB cases in 2021 and 2022 is a result of disruptions in TB diagnosis and treatment during the COVID-19 pandemic. The reported number of newly diagnosed TB cases decreased

from 7.1 million in 2019 to 5.8 million in 2020 and 6.4 million in 2021. This decline leads to more undiagnosed and untreated cases, impacting TB mortality and increasing transmission. (17,18) A subsequent rise in TB disease cases expected after a lag time due to the progression from infection to disease. The global recovery in TB diagnosis in 2022 primarily affects TB mortality, with a longer timeframe projected for a reversal in the overall increase in TB incidence, in 2023 or 2024 according to previous estimates. (19)

According to WHO Mortality Report 2023, About 1.3 million people died due to the TB disease in the year 2022. Among estimated 167,000 deaths among people with HIV.(20) Additionally, vulnerable populations, such as people living with HIV/AIDS, the elderly, and those with weakened immune systems, are at an increased risk of developing active TB.

1.4.2 Indian Prevalence

According to the WHO Report there is 27% of affected people are from India which is the highest among all affected countries in the world. (21) As per India TB Report 2023 released by TB Division, Ministry of Health and Family Welfare states that 24.22 lakh cases notified India, an increase of over 13% as compared to 2021.(22) This results in an approximate case notification rate of 172 cases per hundred thousand population. Delhi exhibited the highest case notification rate among states, standing at 546 cases per hundred thousand population, Karnataka has notified 111 cases per hundred thousand population, while Kerala recorded the lowest rate at 67 cases per hundred thousand population.(23)

Treatment coverage for estimated TB cases has risen to 80%, indicating a 19% improvement from the previous year. India's initiatives have led to a substantial 16% decrease in TB incidence in 2022 compared to 2015, which is twice the global rate of decline at 8.7%. Over the same period, both in India and globally, TB mortality has experienced an 18% reduction.

1.5 Burden

1.5.1 Economic Burden

The economic burden of tuberculosis (TB) poses significant challenges both in India and globally. In India, TB exerts a considerable economic impact due to factors such as healthcare costs, lost productivity, and the strain on public health resources. The financial burden includes expenses related to diagnosis, treatment, and care, which can be substantial for individuals and

families. Additionally, the indirect costs associated with lost income and productivity further contribute to the economic challenges posed by TB. (24)

On a global scale, TB's economic burden is evident in the form of healthcare expenditures, loss of workforce productivity, and the economic strain on affected individuals, families, and communities. The costs of TB prevention, diagnosis, and treatment, coupled with the societal impact of morbidity and mortality, contribute to the overall economic burden. (25)

Efforts to address the economic burden of TB involve not only improving healthcare infrastructure and access but also implementing effective prevention strategies to reduce the incidence of the disease. By mitigating the economic impact of TB, countries can work towards achieving better health outcomes and sustainable economic development.

1.5.2 Social Burden

Pulmonary tuberculosis (TB) represents a significant social burden in both India and globally. Here is a look at how it impacts societies in these contexts:

1.5.2.1 Indian Perspective

High Burden- India has one of the highest burdens of TB in the world, with millions of new cases reported each year. The large population, high population density, poverty, and inadequate healthcare infrastructure contribute to the spread and impact of TB.

Economic Impact- TB places a substantial economic burden on individuals, families, and the healthcare system in India. The costs associated with diagnosis, treatment, and lost productivity can push affected households further into poverty. (25)(24)

Stigma and Discrimination- Stigma surrounding TB is prevalent in India, leading to discrimination against individuals with the disease. This can affect their ability to access healthcare, secure employment, and maintain social relationships. (26,27)

Drug Resistance- India also faces challenges with drug-resistant TB, which is more difficult and expensive to treat. These further strains healthcare resources and exacerbates the social burden of the disease. (21)

Access to Care- While India has made progress in improving TB diagnosis and treatment through initiatives like the Revised National Tuberculosis Control Program (RNTCP), access to care remains a challenge, particularly in rural and marginalized communities.

1.5.2.2 Global Perspective:

Global Health Threat- TB is a global health threat, affecting countries across the world, particularly in low- and middle-income regions. The social burden of TB is exacerbated in areas with limited resources, weak healthcare systems, and high rates of poverty.(24,28)

Impact on Vulnerable Populations- TB disproportionately affects vulnerable populations such as migrants, refugees, prisoners, and those living with HIV/AIDS. These groups often face additional barriers to accessing healthcare and may experience higher rates of stigma and discrimination. (1)

Globalization and Travel- Globalization and increased travel contribute to the spread of TB across borders. This interconnectedness highlights the need for coordinated efforts at the global level to control TB and mitigate its social impact. (29)

Health inequality- TB is often associated with social determinants of health, including poverty, overcrowded living conditions, and lack of access to healthcare. Addressing these underlying factors is crucial for reducing the social burden of TB on a global scale.

Multidrug-Resistant TB (MDR-TB) and Beyond- The emergence of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) presents additional challenges in TB control efforts globally, requiring innovative approaches to diagnosis, treatment, and prevention. (14,21)

In both India and the world, addressing the social burden of pulmonary TB requires a comprehensive approach that encompasses healthcare system strengthening, poverty alleviation, stigma reduction, and international collaboration.

1.6 Causes and Risk factors.

Pulmonary tuberculosis (PTB) is caused by infection with the bacterium Mycobacterium tuberculosis. While anyone can develop TB if exposed to the bacteria, certain factors increase the risk of infection and progression to active disease. People infected with TB bacteria have a 5–10% lifetime risk of falling ill with TB. (30,31)Here is an overview of the causative and risk factors:

Causative Factor:

Mycobacterium tuberculosis: TB is primarily caused by the bacterium Mycobacterium tuberculosis. It is an airborne pathogen, meaning it spreads through the air when an infected person coughs, sneezes, or speaks, and another person inhales the bacteria-containing droplets.

Risk Factors:

Close Contact with an Infectious Individual: Close and prolonged contact with someone who has active TB disease increases the risk of infection. This is particularly true for household contacts, healthcare workers, and others in close proximity to individuals with TB.

Weak Immune System: Individuals with weakened immune systems are at higher risk of developing active TB disease if infected with Mycobacterium tuberculosis. This includes people living with HIV/AIDS, those undergoing immunosuppressive therapy (such as organ transplant recipients), and individuals with certain medical conditions (e.g., diabetes, malnutrition).

Living Conditions: Overcrowded and poorly ventilated living conditions facilitate the spread of TB. Settings such as prisons, homeless shelters, and refugee camps are at higher risk of TB transmission due to close quarters and limited access to healthcare.

Malnutrition: Malnutrition weakens the immune system, making individuals more susceptible to TB infection and increasing the risk of progression from latent TB infection to active disease.

Substance Abuse: Substance abuse, particularly injection drug use, can weaken the immune system and increase the risk of TB infection and disease.

Smoking: Tobacco smoking damages the lungs and impairs the immune system's ability to fight infections, including TB. Smokers are at increased risk of TB infection and progression to active disease.

Age: While TB can affect individuals of any age, the risk of developing active TB disease is higher in certain age groups, including young children and older adults.

Healthcare Settings: Healthcare workers may be at increased risk of TB infection due to exposure to patients with active disease. Adequate infection control measures, including proper ventilation, use of personal protective equipment, and screening of patients for TB, are essential for reducing the risk of TB transmission in healthcare settings.

Travel to High-Incidence Areas: Traveling to regions with a high prevalence of TB increases the risk of exposure to Mycobacterium tuberculosis. Individuals traveling to or residing in countries with a high burden of TB should be aware of the risks and take precautions to prevent infection.

Drug Resistance: Exposure to drug-resistant strains of Mycobacterium tuberculosis, such as multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), increases the risk of treatment failure and transmission of resistant strains.

Understanding these causative and risk factors is crucial for TB prevention, early detection, and targeted interventions to reduce the burden of pulmonary tuberculosis. Efforts to address TB should focus on both individual-level factors and broader social determinants of health to effectively control and prevent the spread of the disease.

1.7 Signs and Symptoms

Pulmonary tuberculosis (TB) can manifest with a variety of signs and symptoms, which can vary in severity depending on factors such as the stage of the disease, the individual's immune response, and any underlying health conditions. Here is a detailed explanation:

Cough: Persistent cough is one of the hallmark symptoms of pulmonary TB. The cough may start mild but can progressively worsen over time. It is often productive, producing sputum that may be blood-tinged or contain pus.

Fatigue: Individuals with pulmonary TB often experience persistent fatigue, which can interfere with daily activities and lead to decreased energy levels.

Fever: Low-grade fever or fever spikes, especially in the late afternoon or evening, are common symptoms of TB. Fever is typically associated with the body's immune response to the infection.

Night Sweats: Profuse sweating, particularly during sleep, is another characteristic symptom of pulmonary TB. Night sweats are often accompanied by fever and can lead to disrupted sleep patterns.

Weight Loss: Unintentional reduction of weight normal characteristic of pulmonary TB, often due to a combination of decreased appetite, metabolic changes, and the body's efforts to fight the infection.

Loss of Appetite: Many individuals with pulmonary TB experience a loss of appetite, which can contribute to weight loss and nutritional deficiencies.

Chest Pain: Chest pain may be seen as a reason that causes infection of the lung tissue (pleurisy) or enlarged lymph nodes pressing on surrounding structures. The pain may worsen with coughing or deep breathing.

Shortness of Breath: As the infection progresses, individuals may experience shortness of breath, especially during physical exertion or when lying flat (orthopnea).

Hemoptysis: Hemoptysis means coughing up blood, is one of symptoms of pulmonary TB, particularly when there is erosion of blood vessels within the lungs.

These are the main symptoms of the Pulmonary Tuberculosis.(32)

Other Respiratory Symptoms: Additional respiratory symptoms may include wheezing, chest tightness, and a feeling of constriction or discomfort in the chest.

Systemic Symptoms: In severe cases of pulmonary TB or in individuals with weakened immune systems, systemic symptoms such as malaise, chills, and swollen lymph nodes may also be present.

It is important to note that not everyone with pulmonary TB will experience all these symptoms, and the presentation can vary widely from person to person. Additionally, some individuals may have latent TB infection, meaning they are infected with the bacteria but do not have active symptoms. If any person suspects of having PTB or person have been exposed to person with TB, it is important to take the physicians evaluation and get treated for the same is very much necessarily. Early detection and cure are the key to preventing the expansion of PTB that reduces complications.

1.8 Pathophysiology of PTB:

The pathophysiology of pulmonary tuberculosis (TB) involves a complex interaction between the bacterium Mycobacterium tuberculosis (M. tuberculosis) and the host's immune response. Here is a detailed overview of the pathophysiological process: (33)

Transmission: Pulmonary TB is primarily spread through the inhalation of infectious droplets containing M. tuberculosis. When an infected individual coughs, sneezes, or speaks, droplets containing the bacteria are released into the air. When another person inhales these droplets, the bacteria can enter the respiratory tract and establish infection.

Infection: Once inhaled, M. tuberculosis enters the alveoli of the lungs, where it is engulfed by alveolar macrophages, which are part of the innate immune response. However, M. tuberculosis has evolved mechanisms to evade destruction by macrophages and can survive and replicate within these cells.

Formation of Granulomas: In response to the presence of M. tuberculosis, the immune system initiates an inflammatory response, leading to the formation of granulomas. Granulomas are organized structures composed of immune cells, including macrophages, T lymphocytes, and multinucleated giant cells. The purpose of granuloma formation is to contain the infection and prevent its spread to other tissues.

Latent TB Infection (LTBI): In many cases, the immune response can control the infection, leading to a state known as latent TB infection (LTBI). In LTBI, the bacteria remain dormant within granulomas, with no active replication or clinical symptoms. However, persons with LTBI are getting new active Tuberculosis illness if their immunity reduces.

Reactivation: In some cases, particularly when the immune system is compromised, M. tuberculosis can escape from granulomas and begin to replicate, leading to the reactivation of TB disease. Reactivation typically occurs in the apical and posterior segments of the upper lobes of the lungs, where oxygen tension is highest and blood flow is greatest.

Progression to Active TB Disease: When TB disease becomes active, individuals may experience a range of symptoms, including cough, fever, night sweats, weight loss, and fatigue. Active TB disease can spread to other parts of the lungs and body, leading to complications such as pleural effusion, miliary TB, and extrapulmonary TB involving organs such as the brain, kidneys, and bones.

Caseation Necrosis and Cavitation: In active TB disease, the immune response can lead to caseation necrosis, characterized by the formation of necrotic (dead) tissue within granulomas. This necrotic tissue can liquefy, leading to the formation of cavities within the lungs. Cavitation increases the risk of transmission of M. tuberculosis to others and is associated with more severe disease and poorer treatment outcomes.

Immune Response: The host immune response plays a crucial role in determining the outcome of M. tuberculosis infection. While an effective immune response can control the infection and prevent disease progression, an inadequate or dysregulated immune response can lead to uncontrolled bacterial replication and the development of active TB disease.

Drug Resistance: The emergence of drug-resistant strains of M. tuberculosis, such as multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), poses a significant challenge to TB control efforts. Drug resistance can develop due to factors such as inadequate treatment regimens, poor treatment adherence, and transmission of resistant strains. Understanding the pathophysiology of pulmonary TB is essential for the development of effective prevention strategies, early detection methods, and targeted treatments to control the spread of the disease and reduce its burden on individuals and communities.

1.9 Diagnosis of PTB

Pulmonary tuberculosis (TB) remains a major global health concern, necessitating timely and accurate diagnosis for effective management and control. This chapter provides an extensive

examination of the diagnostic methods employed in identifying pulmonary TB, delving into their principles, strengths, limitations, and implications for clinical practice.

Clinical Presentation and Evaluation:

Diagnosing pulmonary TB begins with a thorough clinical evaluation, where healthcare providers assess the patient's medical history, symptoms, and risk factors. The main symptoms of pulmonary Tuberculosis include constant cough, fever, night sweats, weight reduction, and hemoptysis. Additionally, close contact with an infectious TB case, immunosuppression, and comorbidities are crucial risk factors to consider during evaluation.

Microbiological Diagnosis:

Microbiological methods serve as the cornerstone for diagnosing pulmonary TB, allowing for the direct detection of Mycobacterium tuberculosis (M. tuberculosis) in clinical specimens. **Key microbiological techniques include:** (34)

Sputum Smear Microscopy: This conventional method involves staining sputum samples with a fluorescent or acid-fast stain and examining them under a microscope for acid-fast bacilli (AFB), indicative of M. tuberculosis infection. While simple and inexpensive, sputum smear microscopy has limitations in sensitivity, particularly in paucibacillary cases.

Culture: Culturing M. tuberculosis from respiratory specimens remains the gold standard for TB diagnosis. Culturing allows for the detection of viable bacteria and facilitates drug susceptibility testing to guide treatment decisions. However, culture-based methods are time-consuming, requiring weeks for results to be available.

Nucleic Acid Amplification Tests (NAATs): NAATs, such as polymerase chain reaction (PCR) assays, detect M. tuberculosis genetic material with high sensitivity and specificity. These tests provide rapid results and are particularly useful when sputum smear microscopy is negative or when there is a need for rapid diagnosis.

Line Probe Assays (LPAs): LPAs are molecular assays that detect both M. tuberculosis presence and mutations associated with drug resistance directly from clinical specimens. LPAs offer rapid detection of drug-resistant TB strains, enabling timely initiation of appropriate treatment.

Radiological Imaging:

Radiological imaging serves as a complementary tool in the diagnosis of pulmonary TB, offering insights into the extent and severity of lung involvement. Common imaging modalities include:

1. Chest X-ray (CXR): CXR is often the initial imaging modality used in suspected pulmonary TB cases. Typical CXR findings include upper lobe infiltrates, cavities, and lymphadenopathy. However, CXR lacks specificity and cannot distinguish TB from other pulmonary diseases.

2. Computed Tomography (CT): CT imaging provides higher sensitivity and specificity compared to CXR, offering detailed information about parenchymal and extra-parenchymal involvement in pulmonary TB. CT findings may include nodules, cavities, consolidations, and mediastinal lymphadenopathy.

Other Diagnostic Modalities

In addition to microbiological and radiological methods, other diagnostic modalities may be utilized in specific clinical scenarios:

Bronchoscopy: Bronchoscopy with bronchoalveolar lavage (BAL) or transbronchial biopsy may be employed to obtain respiratory samples for microbiological testing, particularly in cases of suspected TB with negative sputum smears.

GeneXpert MTB/RIF Assay: This automated NAAT detects M. tuberculosis and rifampicin resistance directly from sputum samples. GeneXpert offers rapid and accurate diagnosis of TB, especially in settings with limited laboratory infrastructure.

Diagnosing pulmonary TB necessitates a multifaceted approach, integrating clinical evaluation, microbiological testing, radiological imaging, and, in some cases, additional diagnostic modalities. Timely and accurate diagnosis is paramount for initiating appropriate treatment, preventing transmission, and mitigating the global burden of TB. Continued research and innovation in diagnostic technologies are imperative for enhancing TB diagnosis, particularly in resource-limited settings with high disease prevalence.

Conventional Management of PTB

Pulmonary tuberculosis (TB) requires a comprehensive management approach to effectively treat the infection, prevent transmission, and reduce the risk of complications. This chapter outlines the conventional management strategies employed in the treatment of pulmonary TB, including pharmacological interventions, patient education, and monitoring protocols.

Diagnosis Confirmation

Before initiating treatment, confirmation of the diagnosis of pulmonary TB is essential. This typically involves a combination of clinical evaluation, microbiological testing (such as sputum smear microscopy, culture, and nucleic acid amplification tests), and radiological imaging (chest X-ray or computed tomography) to establish the presence of Mycobacterium tuberculosis and assess disease severity.

Pharmacological Treatment

The cornerstone of pharmacological treatment for pulmonary TB is a combination of antibiotics known as anti-tuberculosis medications. The standard regimen for drug-susceptible pulmonary TB typically consists of an initial intensive phase followed by a continuation phase. (3,35) Commonly used first-line anti-TB drugs include:

Isoniazid (INH)

Rifampicin (RIF)

Pyrazinamide (PZA)

Ethambutol (EMB)

Intensive Phase:

During the intensive phase, patients receive a combination of all four first-line drugs daily for a period of 2 months. (4) This phase aims to rapidly reduce the bacterial load and suppress active TB disease. Directly Observed Therapy (DOT) is often recommended to ensure medication adherence and treatment success.

Continuation Phase

Following the intensive phase, patients transition to the continuation phase, where they typically receive a combination of INH and RIF for an additional 4 to 7 months.(36) This phase aims to consolidate treatment gains, prevent disease relapse, and achieve cure. The total duration of treatment may vary depending on factors such as disease severity, drug susceptibility, and patient response.

Monitoring and Adverse Effects

Throughout the treatment course, patients undergo regular monitoring to assess treatment response, medication adherence, and potential adverse effects. Common adverse effects of anti-TB medications include hepatotoxicity, gastrointestinal disturbances, peripheral neuropathy, and visual disturbances. Healthcare providers closely monitor patients for signs of adverse effects and adjust treatment regimens, as necessary.

Patient Education and Support

Patient education and support are integral components of pulmonary TB management, empowering patients to actively participate in their treatment and adhere to medication regimens. Key aspects of patient education include:

1. Understanding the importance of medication adherence
2. Recognizing and managing adverse effects
3. Practicing infection control measures to prevent TB transmission to others.
4. Understanding the significance of completing the full treatment course

5. Engaging in lifestyle modifications to support treatment success, such as maintaining a nutritious diet and avoiding alcohol and tobacco use.

Conventional management of pulmonary TB involves a multidimensional approach, encompassing pharmacological interventions, patient education, monitoring protocols, and support services. By adhering to established treatment regimens, patients can achieve cure, prevent disease relapse, and contribute to global TB control efforts. Ongoing research and innovation are essential to optimize treatment outcomes and address emerging challenges in TB management, such as drug resistance and co-infections with HIV.

1.10. Justification/Need for the research:

The prevalence of Tuberculosis high and Tuberculosis is responsible for the highest mortality rate in the world after HIV disease. In 2017 ten million people have active tuberculosis in the world out of which 1.6 million deaths occurred. (37) Globally every 24 seconds there is a death due to tuberculosis. (1)

India contributes the highest TB patients in the world and highest mortality in the world is the biggest concern now. (38,39) More than half of the affected people belong to the middle class and poor people from rural backgrounds. The World Health Organization (WHO) has set the goal of a 90% reduction in global TB incidence by 2030 when compared to 2015. (38)

India is closer to achieving the Sustainable development goal of ending tuberculosis (TB). Recently Revised National Tuberculosis Control Programme (RNTCP) has been renamed as National Tuberculosis End Programme (NTEP) and main motive is to end TB by 2025. (39) Now with present NTEP and Yoga there are no studies have been conducted so far.

National Tuberculosis Elimination Programme is a new scheme and had improvement in success rate but still not met treatment success rate of 85% target (current success rate is around 70% and had many challenges like addressing psychological issues depression & anxiety, health related quality of life and pulmonary rehabilitation. (39)

The literature on pulmonary tuberculosis and Yoga are extremely limited. The studies on pulmonary function test and pulmonary tuberculosis are not yet established. Previous study on Pulmonary function test conducted on healthy individuals shows there is improvement in the pulmonary parameters, and it suggests that Yoga can be alternate or adjuvant therapy for respiratory diseases. (40)

In other studies, Naveen K Visveswaraya et al., (2003) had not been a holistic approach as in case of integrated Yoga at present and less parameters had been used, they have given short

term, and psychological factors and health related quality of life has not been assessed. It is done in 2003 but after that there are several changes has undergone in addressing the issues in both allopathic as well as in Yoga. (41)

The literature shows lacunae to address the health-Related Quality of Life (HRQOL) as PTB patients will have exceptionally low quality of life during the phase of treatment regime as well as after the treatment. (14,38,42–44) Another study conducted in Kashmir and North India reveals there should be a more focus solution to enhance the HRQOL that creates the psychological distress in Pulmonary Tuberculosis Patients. (26)

Previous studied on Indian scenario of quality of life and psychological assessment in tuberculosis patients revealed that TB patients will have poor quality of life as well as facing psychological distress during the treatment period. (42) In the same study reveals that there is a lack of knowledge in addressing the psychological distress and there is a necessary to include counselling. Yoga could be a better management in the psychological aspects to address possible solution.

Now the traditional system of medicine has fewer side effects, non-invasive, inexpensive so keen on adding a traditional system of medicine throughout healthcare practices will give scientific evidence so that Integrated Yoga as alternative therapy along with the regular Anti-Tuberculosis Treatment regime will be possible add-on therapy. (45,46)

So, the overall need of integrated Yoga is helpful in increasing the lung capacities or respiratory efficiency in both healthy as well as in diseased conditions. Yoga also known for the beneficiary effects on physical, mental level functions and besides improving the quality of life.

2 CHAPTER-2: Literature Review

2.1 Epidemiology

The epidemiology of pulmonary tuberculosis (TB) encompasses the distribution, determinants, and dynamics of TB transmission, prevalence, incidence, and outcomes at the population level. Understanding the epidemiology of pulmonary TB is crucial for developing effective prevention, control, and treatment strategies. Here's an overview of key epidemiological aspects:

1. **Global Burden**:
    - Pulmonary TB remains a major global health threat, with significant morbidity and mortality worldwide. (1)
    - In 2020, an estimated 10 million people developed TB globally, with approximately 1.5 million deaths attributed to TB, including 200,000 deaths among individuals co-infected with HIV. (1,16,47)
    - According to the World Health Organization (WHO), TB is one of the top 10 causes of death globally and the leading cause of death from a single infectious agent, surpassing HIV/AIDS. (48,49)
2. **Regional Variation**:
    - TB burden varies widely across regions and countries, with the highest burden concentrated in low- and middle-income countries, particularly in sub-Saharan Africa, Southeast Asia, and the Western Pacific region. (13,14)
    - In 2022, over two-thirds of global TB cases were concentrated in eight countries: India (27%), Indonesia (10%), China (7.1%), the Philippines (7.0%), Pakistan (5.7%), Nigeria (4.5%), Bangladesh (3.6%), and the Democratic Republic of the Congo (3.0%) of all TB affected people. (15)
    - Factors contributing to regional disparities in TB burden include differences in healthcare infrastructure, socio-economic conditions, access to healthcare services, and prevalence of risk factors such as HIV/AIDS, malnutrition, and tobacco smoking.
3. **High-Risk Populations**:
    - Certain populations are disproportionately affected by pulmonary TB, including individuals living with HIV/AIDS, prisoners, refugees, migrants, homeless individuals, and marginalized communities.

- Factors such as overcrowded living conditions, poor ventilation, inadequate access to healthcare, and socio-economic deprivation contribute to the heightened risk of TB transmission and disease progression in these populations.

4. **Transmission Dynamics**:
    - Pulmonary TB is primarily transmitted through the inhalation of aerosolized droplets containing Mycobacterium tuberculosis (MTB) bacteria expelled by individuals with infectious TB.
    - Close and prolonged contact with infectious individuals, particularly in crowded and poorly ventilated environments, facilitates TB transmission.
    - The risk of TB transmission is influenced by factors such as the infectiousness of the index case, the duration and proximity of exposure, and the immune status of contacts.
5. **Drug Resistance**:
    - The emergence and spread of drug-resistant TB strains, including multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), pose significant challenges to TB control efforts.
    - Drug resistance develops primarily due to inadequate treatment regimens, incomplete treatment courses, and poor adherence to TB medications.
    - Drug-resistant TB is associated with higher morbidity, mortality, and healthcare costs compared to drug-susceptible TB.
6. **Diagnostic and Treatment Gaps**:
    - Despite significant progress in TB control efforts, many individuals with TB remain undiagnosed, untreated, or inadequately treated.
    - Diagnostic gaps arise from limitations in access to TB diagnostics, healthcare-seeking behaviour, and healthcare provider awareness.
    - Treatment gaps result from barriers to accessing TB treatment services, medication stockouts, treatment interruptions, and suboptimal treatment adherence.

7. **Challenges and Opportunities**:
    - Addressing the epidemiology of pulmonary TB requires a comprehensive, multi-sectoral approach that addresses underlying socio-economic

determinants, strengthens healthcare systems, and enhances TB prevention, diagnosis, and treatment services.

- Innovations in TB diagnostics, treatment regimens, and vaccines offer promising opportunities for accelerating progress towards TB elimination goals.

The epidemiology of pulmonary TB reflects a complex interplay of social, environmental, biological, and healthcare system factors. Efforts to control TB must be tailored to local epidemiological contexts and prioritize interventions that address underlying drivers of TB transmission and disease burden.

2.2 Burden of TB on Individual Life

The burden of tuberculosis (TB) on individual lives is a multifaceted issue that has been extensively documented in the literature. Research has highlighted the profound physical, psychological, social, and economic impacts of TB on affected individuals. The literature provides insight into the various dimensions of this burden:

1. **Physical Health Effects:** Several research studies have investigated the physical implications of TB on patients. TB commonly manifests with symptoms like persistent cough, fever, fatigue, and weight loss, which can greatly hinder an individual's well-being. (51) If TB is not treated or managed properly, it can result in serious complications such as lung impairment, respiratory dysfunction, and potentially fatal outcomes.

2. **Psychological Distress**: Living with TB can result in considerable psychological distress for affected individuals. Stigma, fear of transmission, and the uncertainty of treatment outcomes contribute to anxiety, depression, and social isolation. Studies have shown that TB patients often experience feelings of shame, guilt, and low self-esteem, which can further exacerbate their mental health burden. (15,52–54)

3. **Social Stigma and Discrimination**: TB is often associated with social stigma and discrimination, particularly in communities where misconceptions about the disease prevail. Individuals with TB may face rejection, ostracism, and discrimination from family members, friends, and the broader community. Stigma can impede access to healthcare services, delay diagnosis and treatment initiation, and hinder social integration and support. (27,35,55)

4. **Financial Hardship**: TB imposes significant economic burdens on individuals and their families. Direct costs related to medical care, including diagnostic tests, medications, and hospitalization, can be substantial, especially in low-income settings where access to affordable healthcare is limited. Indirect costs, such as loss of income due to illness, reduced productivity, and caregiving responsibilities, further compound the financial strain experienced by TB patients and their households.(24)

5. **Long-term Consequences**: Ater the successful completion of treatment, PTB can have long standing consequences for individuals. Lung impairments, impaired respiratory function, and chronic health conditions may persist, affecting individuals' ability to work, engage in physical activities, and lead fulfilling lives. Moreover, PTB survivors may continue to experience psychological distress and social challenges related to stigma and discrimination.(9,56)

Overall, the literature underscores the significant burden of TB on individual lives, encompassing physical health, psychological well-being, social relationships, and economic stability. Addressing this burden requires a holistic approach that encompasses medical care, psychosocial support, stigma reduction efforts, and socioeconomic interventions to improve the lives of those affected by TB.

2.3 Causes of PTB

Pulmonary tuberculosis (TB) mainly results from infection with the bacterium called Mycobacterium tuberculosis (MTB). Transmission of MTB happens through inhaling airborne droplets containing the bacteria, typically released when someone with active pulmonary TB coughs, sneezes, or talks. Upon inhalation, the MTB bacteria can infect the lungs and potentially spread to other areas of the body. These are the primary causes and factors contributing to pulmonary TB.

Mycobacterium tuberculosis Infection: Infection with Mycobacterium tuberculosis (MTB) is the primary factor behind pulmonary TB. MTB is highly contagious, mainly impacting the lungs but also capable of affecting other organs, resulting in extrapulmonary TB. (2)

Airborne Transmission: Transmission occurs through inhaling aerosolized droplets containing MTB, particularly in poorly ventilated areas where individuals with active TB cough or sneeze, leading to close and prolonged exposure.(26)

Close Contact with Infectious Individuals: Individuals living or working in close proximity to someone with active pulmonary TB are at increased risk of infection. Household contacts,

healthcare workers, and individuals in congregate settings such as prisons and homeless shelters are particularly vulnerable. (57)

Immune System Factors: Host susceptibility to TB is influenced by various factors related to the immune system. Immunocompromised individuals, such as those with HIV/AIDS, organ transplant recipients, and individuals receiving immunosuppressive therapy, are at higher risk of developing active TB disease due to impaired immune responses. (32)

Malnutrition and Poor Health: Malnutrition, especially deficiencies in essential nutrients like vitamin D and zinc, can weaken the immune system and increase susceptibility to TB infection and disease progression. (58)

HIV/AIDS: HIV/AIDS is a significant risk factor for the development of pulmonary TB. HIV weakens the immune system, making individuals more susceptible to TB infection and increasing the likelihood of TB reactivation in those with latent TB infection. (50)

Smoking: Tobacco smoking damages the respiratory tract and impairs lung function, increasing the risk of TB infection and disease progression. Smokers with TB are also more likely to experience severe TB symptoms and complications. (59)

Drug Resistance: The emergence and spread of drug-resistant strains of MTB, particularly multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), pose significant challenges to TB control efforts. Drug resistance can develop due to inadequate treatment regimens, incomplete treatment courses, and poor adherence to TB medications. (3)

Socioeconomic Factors: Poverty overcrowded living conditions, inadequate access to healthcare, and limited resources for TB prevention, diagnosis, and treatment contribute to the burden of pulmonary TB, particularly in resource-limited settings and marginalized populations.(60)

Understanding these causes and risk factors is essential for developing effective strategies for TB prevention, early detection, and treatment. Comprehensive TB control programs aim to address these factors through measures such as case finding, contact tracing, TB screening, infection control, and access to quality healthcare services.

2.4 Mental Health and PTB

The relationship between mental health and Pulmonary tuberculosis (PTB) is complex. Mental illness can be a silent driver of the global TB epidemic, associated with drug resistance, transmission, recurrence, and TB-related death. Severe mental disorders increase the risk of TB acquisition and transmission, and diagnosis with TB can also increase the risk of psychiatric comorbidity.(61,62) The impact of mental health on TB patients has hindered their wellbeing both emotionally and spiritually which makes it a hindrance to seeking a healthy behaviour, hence affecting treatment outcomes in a long round.(63) The following were the frequent mental conditions that are observed in the PTB patients.

2.4.1 Depression and Anxiety in PTB

The co-occurrence of depression and anxiety in individuals with pulmonary tuberculosis (TB) has garnered significant attention in the scientific literature due to its implications for patient outcomes, treatment adherence, and quality of life.(52,57) Here's a review of the literature on depression and anxiety in pulmonary TB:

Table-1: Summary of research articles- Depression and Anxiety in PTB

SL.NO	Author& Year of publication	Study design/ Sample size	Methodology	Result
01	*Vidyullatha Peddireddy,2016* (64)	Review NA	A systematic review was carried out on research papers focusing on the quality of life in tuberculosis (TB) and the impact of psychological interventions on treatment outcomes. However, it's noteworthy that these psychological interventions are not currently implemented in clinical settings in India.	Tuberculosis patients commonly face heightened stress levels and a decline in quality of life. In India, like elsewhere, TB patients endure significant psychological stress. It's imperative for governmental and non-governmental organizations to urgently develop strategies to incorporate mandatory psychological

				interventions during TB treatment.
02	Shabir Ahmad Dar et al.,2018 (26)	Prospective study/ 198	This study was prospective and spanned one and a half years. Quality of life (QOL) was evaluated both at the beginning and the conclusion of the intensive phase. The "World Health Organization's Quality of Life Brief" tool utilized for QOL assessment.	We have determined that "Health-Related Quality of Life (HRQOL)" is notably diminished in affected once in pulmonary tuberculosis (PTB), & it demonstrates rapid & significant improvement during the DOTS-based intensive phase of treatment. It is crucial to place particular emphasis on addressing the reduction of stigmatization in TB management to alleviate psychological distress effectively.
03	A. C. Sweetland et al.,2019 (28)	Questionnaire based survey/ Twenty-six countries	Used the questionnaire survey of national tuberculosis programs directors from twenty-six republics with a regular Questionnaire.	Currently, national tuberculosis programs (NTPs) typically don't include the management of mental disorders as part of their standard procedures. However, there is a notable openness to the idea, presenting a promising chance to incorporate strategies for addressing both tuberculosis and mental health issues into the policies and recommendations of NTPs globally.

SL. NO	Author& Year of publication	Study design/ Sample size	Methodology	Result
04	Ashutosh N. Aggarwal,2019 (65)	Review NA	To conduct this review, we searched the PubMed database using terms such as quality of life, health status, and tuberculosis, and identified further relevant publications through reviewing the references of selected articles. The quality of life in individuals with tuberculosis is negatively affected by factors like reduced ability to work, social stigma, and psychological challenges.	While it's been consistently observed that quality of life (QOL) tends to increase during standard anti-tuberculosis treatment, numerous patients still experience lasting impairment. It's clear that there's a necessity to integrate QOL evaluation as supplementary outcome indicators within tuberculosis control initiatives.
05	Kehong Zhang et al., (2019) (66)	Review/ NA	According to clinical observations, there appears to be a two-way relationship between tuberculosis and depression, with significant similarity in symptoms between the two conditions. The onset or recurrence of TB could potentially trigger depression, possibly due to the body's inflammatory reaction with disruption of the HPA axis in the host.	It's noteworthy that depression by itself poses a risk for tuberculosis. Throughout anti-TB therapy, it's common to encounter challenges such as noncompliance with treatment and experiencing adverse effects, both of which can result in prolonged recovery or exacerbation of depression-like symptoms alongside TB.
06	Lew Addis Alene et al., 2018 (5)	Systematic Review & Meta-Analysis/ NA	We conducted searches across multiple databases including PubMed, SCOPUS, ProQuest, Web of Science, and PsycINFO to identify studies reporting on	This review revealed that a significant portion of MDR-TB patients experience compromised mental health and social functioning, as

			mental health disorders, social stressors, and health-related quality of life among patients with multidrug-resistant tuberculosis (MDR-TB). Selection of studies followed predefined criteria, and data extraction was carried out by 2 authors.	evidenced by the reported low health-related quality of life. Consequently, there is a considerable necessity to incorporate mental health services, social protection, and social support into the clinical and programmatic management of MDR-TB.

07	Argiro Pachi et al.,2013 (67)	Systematic review/ NA	*Search Strategy:* Using different key words combination on the PubMed search was carried out. Articles only in English were selected, and dates of published were between 1950 to 2012.	Included in the study were reports highlighting elevated prevalence rates of psychiatric comorbidities, notably depression, along with specific psychological responses and perceptions of the disease. Additionally, reviews suggesting psychiatric problems as harmful effects of anti-TB tablets were considered.
08	Jacqueline V. Lara-Espinosa*, Rogelio Hernández-Pando,2021 (52)	Systematic Review/ NA	This review consolidates epidemiological data linking tuberculosis, depression, and anxiety, along with elucidating biological mechanisms that could account for the association between TB, depression, and anxiety.	Tuberculosis, anxiety, and depression are prevalent diseases within the population, posing significant public health challenges. Notably, they share common risk factors and exhibit a syndemic relationship, wherein the presence of one condition promotes the development or exacerbation of the others. There exists substantial comorbidity

				between TB and mental health issues, emphasizing the importance of integrating treatment for depression and anxiety into the comprehensive care of TB patients.
09	Mina Chandra et al.,2019 (68)	Review Article/ NA	PubMed & Google Scholar relevant identifying research was carried out using the appropriate words for search.	The Depression-TB Syndemic is prevalent and characterized by a bidirectional relationship. Depression correlates with a higher hazard ratio and elevated prevalence of tuberculosis. Independently, depression is connected to amplified illness, death, drug resistance, risk of TB happening again, and societal spreading of TB.

1. Prevalence and Burden:

Numerous studies have documented elevated rates of depression and anxiety among individuals with pulmonary TB compared to the general population.

A systematic review and meta-analysis found that the prevalence of depression among TB patients ranged from 5% to 44%, while the prevalence of anxiety ranged from 7% to 59%, depending on factors such as study population, assessment tools, and geographical location. (69)

The burden of depression and anxiety in pulmonary TB patients is associated with increased morbidity, mortality, treatment non-adherence, and poor treatment outcomes.

2. Biopsychosocial Factors:

The aetiology of depression and anxiety in pulmonary TB is multifactorial, involving complex interactions between biological, psychological, and social determinants. (68)

Biological factors include the neuroimmune response to TB infection, alterations in neurotransmitter systems (e.g., serotonin, dopamine), and comorbid medical conditions (e.g., HIV/AIDS, diabetes mellitus) that predispose individuals to mood and anxiety disorders.

Psychosocial factors such as stigma, social isolation, economic hardship, disrupted social roles, and loss of productivity contribute to psychological distress and exacerbate symptoms of depression and anxiety in TB patients.

3. Impact on Treatment Adherence and Outcomes:

Depression and anxiety in pulmonary TB patients are associated with decreased treatment adherence, delayed diagnosis, prolonged treatment duration, and increased risk of treatment failure, relapse, and mortality. (35,70,71)

Psychological symptoms may interfere with medication adherence, clinic attendance, and engagement in TB care, leading to suboptimal treatment responses and ongoing TB transmission within communities.

4. Screening and Assessment:

Routine screening for depression and anxiety in pulmonary TB patients is recommended to identify individuals at risk and facilitate timely intervention.

Usually for screening tools such as the Patient Health Questionnaire (PHQ-9) for depression and the Generalized Anxiety Disorder (GAD-7) scale for anxiety are widely used in clinical practice and research to assess symptom severity and monitor treatment response. But in this study, we have used Hamilton Depression Rating Scale (HDRS)

5. Intervention Strategies:

Integrated care models that address both physical and mental health needs have shown promise in improving outcomes for pulmonary TB patients with depression and anxiety.

Psychosocial interventions, such as cognitive-behavioural therapy (CBT), psychoeducation, counselling, and peer support, may help alleviate symptoms, improve coping strategies, and enhance treatment adherence.(72)

Collaborative care models involving multidisciplinary teams of healthcare providers, including primary care physicians, nurses, mental health specialists, and social workers, facilitate comprehensive assessment, treatment planning, and coordination of care for TB patients with comorbid depression and anxiety.

The literature highlights the significant burden of depression and anxiety in pulmonary TB patients and underscores the importance of integrated approaches to address mental health needs within TB care settings. Early identification, comprehensive assessment, and evidence-based interventions are essential to improve outcomes and enhance the quality of life for individuals living with pulmonary TB and comorbid mood and anxiety disorders.

2.4.2 Depression and PTB

Depression and pulmonary tuberculosis (TB) represent significant public health challenges globally, with overlapping impacts on individuals' health and well-being. This review aims to explore the complex relationship between depression and pulmonary TB, including their prevalence, bidirectional influences, underlying mechanisms, impact on treatment outcomes, and intervention strategies.

1. **Prevalence of Depression in Pulmonary TB**:
    - Numerous studies have reported elevated rates of depression among individuals with pulmonary TB compared to the general population. (15,70,71)
    - Prevalence rates vary widely across studies, influenced by factors such as geographical location, study population characteristics, and assessment methods.
    - Depression in TB patients is associated with poorer treatment adherence, increased morbidity, and reduced quality of life. (35,61,71)
2. **Impact of Depression on Pulmonary TB**:
    - Depression can negatively impact TB treatment outcomes, leading to delays in diagnosis, prolonged treatment duration, and increased risk of treatment failure and relapse. (57)
    - Psychological distress may exacerbate TB-related symptoms, impairing patients' ability to cope with the challenges of TB treatment and management.
    - Depression in TB patients is associated with increased healthcare utilization, healthcare costs, and social stigma.

3. **Mechanisms Underlying the Depression-TB Link**:
    - Biopsychosocial mechanisms contribute to the complex relationship between depression and pulmonary TB.
    - Biological factors include dysregulation of the hypothalamic-pituitary-adrenal (HPA) axis, alterations in neurotransmitter systems (e.g., serotonin, dopamine), and immune dysregulation. (52,73)
    - Psychosocial factors such as social isolation, stigma, and socio-economic disparities contribute to the development and exacerbation of depression in TB patients. (74)
4. **Bidirectional Influences and Complexities**:
    - The connection between depression and pulmonary TB is unique two-way association, each condition influencing the course and outcomes of the other.
    - TB-related symptoms and treatment side effects may exacerbate depressive symptoms, while depression can impair immune function and increase susceptibility to TB infection and disease progression. (66,73,75)
    - Contextual factors, including cultural beliefs, healthcare access, and social support networks, shape the interplay between depression and TB.
5. **Intervention Strategies**:
    - Integrated care models that address both physical and mental health needs are essential for optimizing outcomes in individuals with coexisting depression and pulmonary TB.
    - Psychosocial interventions, such as cognitive-behavioural therapy, psychoeducation, and peer support, can help alleviate depressive symptoms and improve TB treatment adherence.
    - Collaborative care approaches involving multidisciplinary teams of healthcare providers facilitate comprehensive assessment, treatment planning, and coordination of care for TB patients with comorbid depression.

The connection between depression and pulmonary Tuberculosis is complex and multifaceted, with implications for diagnosis, treatment, and management. Comprehensive care models that integrate mental health screening, assessment, and intervention are essential for improving outcomes and enhancing the well-being of individuals living with both conditions.

2.4.3 Quality of Life and PTB

Quality of life (QoL) is a multidimensional concept that encompasses an individual's physical, psychological, social, and environmental well-being. Pulmonary tuberculosis (TB) can significantly impact various aspects of a person's quality of life, both during active disease and in the post-treatment phase.

Table-3: Summary of research articles on Quality of Life and PTB

SL. NO	Author & Publication ID	Study design/ Sample size	Participants	Findings
01	Xiaowei Zuo, et al.,2022 (76)	RCT/ 461	PTB Patients	Cognitive Behavioral Therapy has the potential to alleviate symptoms of anxiety &depression and enhance the QOL for individuals diagnosed with PTB.
02	Donna de Grass, et al.,2022 (77)	Pilot study/ 67	PTB Patients	The study's findings offer encouragement for additional exploration and adoption of a pulmonary rehabilitation program for patients with pulmonary tuberculosis.
03	Zhaojia Xu, et al.,2022 (78)	RCT/ 150	PTB patients	The combination of thorough nursing intervention alongside respiratory functional exercises demonstrates notable clinical efficacy in enhancing the pulmonary function, self-care capability, and quality of life among patients diagnosed with pulmonary tuberculosis.
04	V G Sharan Kumar, et al.,2022 (8)	RCT/ 46	PTB patients	Individualized dietary counseling was discovered to yield beneficial effects in Body Mass Index & albumin levels within the intervention group, particularly among those classified as underweight. Additionally, improvements were noted in the quality of life as assessed by the St.

				George's Respiratory Questionnaire (SGRQ).
05	Jacob Nignan Nabei et al., 2024 (79)	Cross-sectional Study/ 213	PTB Patients	Northern region of the Ghana has very low quality of life in the tuberculosis patients. There is a need for the enhance the QOL by policy making organizations.
06	Wei Yuan et al., 2024 (80)	RCT/ 60	PTB Patients	Quality of Life is enhanced by using Integrated Nursing also with psychological counseling in PTB patients with Lung cancer.

Here's a detailed exploration of the relationship between quality of life and pulmonary TB:

1. **Physical Well-being**:
    - During active pulmonary TB, individuals may experience symptoms such as cough, fever, fatigue, chest pain, and shortness of breath, which can significantly impair physical functioning and overall well-being.
    - TB-related symptoms may interfere with daily activities, work, and social participation, leading to functional limitations and reduced mobility.
    - Long-term consequences of pulmonary TB, such as lung damage, respiratory impairment, and chronic complications, can further impact physical health and quality of life even after successful treatment.
2. **Psychological Well-being**:
    - Pulmonary TB is often accompanied by psychological distress, including anxiety, depression, fear, and stigma.
    - The diagnosis of TB and the associated social stigma can cause feelings of shame, guilt, and isolation, leading to psychological symptoms and impaired mental health.
    - Psychological distress may exacerbate TB-related symptoms, impair coping mechanisms, and contribute to treatment non-adherence, further compromising quality of life.
3. **Social Well-being**:
    - Pulmonary TB can disrupt social relationships, family dynamics, and community integration, leading to social isolation and withdrawal.

- Stigma associated with TB may result in discrimination, social rejection, and loss of social support networks, exacerbating feelings of loneliness and alienation.
- Social determinants such as poverty, unemployment, and housing instability may exacerbate social vulnerabilities and negatively impact quality of life among TB patients.

4. **Emotional Well-being**:
    - The emotional toll of pulmonary TB, including fear of disease progression, uncertainty about treatment outcomes, and concerns about transmission to others, can be significant.
    - Emotional distress may manifest as feelings of sadness, hopelessness, frustration, and despair, affecting overall emotional well-being and resilience.
    - Coping strategies, social support, and access to mental health services play critical roles in mitigating emotional distress and improving quality of life among TB patients.
5. **Environmental Factors**:
    - Environmental factors, such as living conditions, access to healthcare, and socio-economic status, can influence the quality of life of individuals with pulmonary TB.
    - Poor housing conditions, overcrowding, and inadequate sanitation facilities may increase the risk of TB transmission and exacerbate TB-related morbidity and mortality.
    - Access to timely diagnosis, quality healthcare services, and social support programs can enhance environmental conditions and improve quality of life outcomes among TB patients.

Pulmonary TB can have profound effects on various dimensions of quality of life, including physical, psychological, social, and environmental well-being. Recognizing and addressing the multidimensional impact of TB on quality of life is essential for providing holistic, patient-centred care and improving treatment outcomes. Comprehensive TB management strategies should encompass interventions aimed at enhancing quality of life, promoting mental health, addressing social determinants of health, and supporting individuals to regain optimal functioning and well-being.

2.5 Yoga and Pulmonary Function Tests (PFT):

There are very few studies have been conducted on Yoga and Pulmonary Tuberculosis. Yoga has improved the pulmonary capacities in the Pulmonary TB patients. Some of them are explained in detailed in Table-2 as follows.

Table-2: Summary of research articles in Yoga and PFT

SL. NO	Author & Publication Year	Study design/ Sample size	Methodology	Result & Conclusion
01	Nk Visweswaraiah, Telles s.,2004 (81)	RCT/ 73	Random allocation of subjects into Yoga and breath awareness group. The Yoga group practiced Yoga along with standard care. **Outcome measures:** FEV, FVC, Weight, symptom scores	After two months, the Yoga group exhibited noteworthy decreases in symptom scores and increases in weight, Forced Vital Capacity (FVC), and Forced Expiratory Volume in one second (FEV1). Conversely, the breath awareness group... The enhanced condition of infection, radiographic findings, FVC, weight gain, and symptom reduction observed in the Yoga group indicate that Yoga could play a complementary role in managing pulmonary TB.
02	Ajay Kumar Singh et al., 2019 (82)	COHORT study/45	FVC, FEV1, FEV1/FVC ratio, and (PEFR) were measured	Observed the statistically significant results in the PFT values were observed. Demonstrates the complimentary role of Yoga in improving PFT values
03	A Mooventhan et al.,2014 (51)	Case Reports	Weight, BMI, PFT, HRQOL were measured.	All the parameters were improved after the Yoga intervention. Yogic breathing technique with Antituberculosis treatment yields positive response.

2.6 NTEP and PTB (Standard of Care)

The National Tuberculosis Elimination Program (NTEP) sets the standard of care for the treatment of pulmonary tuberculosis (PTB), encompassing a comprehensive approach to

diagnosis, treatment, and control. Within the framework of NTEP, the standard of care treatment for pulmonary TB is guided by evidence-based guidelines and protocols aimed at achieving optimal clinical outcomes and reducing TB transmission. Here's an overview of the NTEP standard of care treatment for pulmonary TB:

1. **Early Diagnosis**:
    - The NTEP emphasizes early diagnosis through systematic screening and diagnostic testing for TB among individuals presenting with symptoms suggestive of pulmonary TB, such as persistent cough, fever, weight loss, and night sweats. (26,73)
    - Diagnostic modalities utilized may include sputum smear microscopy, GeneXpert MTB/RIF testing, chest X-rays, and other imaging studies, as appropriate.
2. **Treatment Initiation**:
    - Once diagnosed, individuals with pulmonary TB are promptly initiated on appropriate treatment regimens according to national or international guidelines, typically consisting of a combination of antibiotics.
    - Standard treatment regimens for drug-susceptible pulmonary TB usually involve a combination of four first-line anti-TB drugs: isoniazid, rifampicin, pyrazinamide, and ethambutol, administered for a specified duration, usually six months.
3. **Directly Observed Treatment (DOT)**:
    - The NTEP often employs Directly Observed Treatment (DOT) as a strategy to ensure treatment adherence and optimize treatment outcomes. (21)
    - DOT involves trained healthcare workers or community volunteers directly observing patients taking their TB medications, typically on a daily or intermittent basis, depending on the treatment regimen.
4. **Patient Education and Support**:
    - Comprehensive patient education and support services are integral components of the standard of care treatment for pulmonary TB.
    - Patients are provided with information about their diagnosis, treatment regimen, potential side effects of medications, and the importance of adherence to treatment.

- Counselling, psychosocial support, and peer support programs may also be offered to address the psychosocial impact of TB and promote treatment adherence.

5. **Monitoring and Follow-Up**:
    - The NTEP monitors treatment progress through regular clinical assessments, sputum examinations, and other laboratory tests as indicated.
    - Systematic follow-up of patients is conducted to monitor treatment response, detect adverse effects, and ensure treatment completion.
6. **Adherence Support and Retention in Care**:
    - The NTEP provides adherence support services to help patients overcome barriers to treatment adherence, such as medication side effects, transportation issues, and socio-economic challenges.
    - Retention in care strategies, including appointment reminders, home visits, and community-based follow-up, are employed to minimize loss to follow-up and ensure continuity of care.

In summary, the NTEP standard of care treatment for pulmonary TB encompasses early diagnosis, prompt initiation of appropriate treatment regimens, adherence support, and comprehensive patient-centred care. By adhering to evidence-based guidelines and protocols, NTEP aims to achieve optimal treatment outcomes and reduce the burden of pulmonary TB on individuals and communities.

2.7 CAM and PTB

Research exploring the use of Complementary and Alternative Medicine (CAM) in the context of pulmonary tuberculosis (PTB) offers insights into various non-conventional approaches that individuals may employ alongside or instead of conventional medical treatments. The literature provides a nuanced understanding of the potential benefits, limitations, and challenges associated with CAM modalities in managing TB. (83,84) Here is a detailed review of the literature on CAM and pulmonary TB:

2.7.1 Traditional Herbal Remedies:

- Traditional herbal remedies have been widely used in many cultures for treating respiratory ailments, including TB. Numerous studies have investigated the efficacy of specific herbs and herbal formulations in combating TB bacteria and alleviating symptoms.

- For example, studies have explored the antimicrobial properties of plants such as garlic, ginger, turmeric, and neem against Mycobacterium tuberculosis. (85) Some herbal formulations have demonstrated potential synergistic effects with conventional TB medications, enhancing their efficacy.
- However, the efficacy and safety of herbal remedies vary widely, and the use of herbal medicines may pose risks of adverse effects, herb-drug interactions, and contamination with toxic substances. Standardization of herbal preparations and rigorous scientific evaluation are essential to ensure their safety and efficacy.

2.7.2 Dietary Supplements:

- Dietary supplements, including vitamins, minerals, and probiotics, have been investigated for their potential role in supporting immune function and improving treatment outcomes in TB patients. (57,86)
- Studies have explored the impact of micronutrient deficiencies, such as vitamin D, vitamin C, zinc, and selenium, on TB susceptibility and progression. Supplementation with these nutrients may help strengthen the immune response and reduce the risk of TB recurrence. (87)
- Additionally, probiotics have been studied for their potential to modulate gut microbiota and enhance host immunity in TB patients. Probiotic supplementation may improve treatment adherence, reduce gastrointestinal side effects of TB medications, and mitigate the risk of antibiotic-associated dysbiosis.
- However, conflicting evidence exists regarding the efficacy of dietary supplements in TB management, and further research is needed to elucidate their role and optimal dosing regimens.

2.7.3 Mind-Body Therapies:

- Mind-body therapies, such as Yoga, meditation, and mindfulness-based interventions, have gained attention for their potential to alleviate psychological distress, improve quality of life, and enhance treatment adherence in TB patients. (88)
- Several studies have explored the effects of Yoga and mindfulness-based stress reduction on mental health outcomes, immune function, and inflammatory markers in TB patients. These interventions may help reduce anxiety, depression, and stigma associated with TB, promoting overall well-being. (89)

- However, the evidence supporting the efficacy of mind-body therapies in TB management remains limited, and more rigorous clinical trials are warranted to establish their effectiveness and elucidate underlying mechanisms of action.

2.7.4 Traditional Healing Practices:

- Traditional healing practices, such as acupuncture, traditional Chinese medicine, Ayurveda, and indigenous healing rituals, are culturally embedded approaches to health and healing that may be utilized by individuals with TB. (90,91)
- While traditional healing practices often emphasize holistic approaches to health, incorporating physical, mental, and spiritual dimensions, their efficacy and safety in TB management have not been systematically evaluated in scientific research.
- Moreover, the integration of traditional healing practices with conventional TB care may raise concerns regarding potential conflicts with evidence-based treatments, delays in seeking appropriate medical care, and adverse interactions between traditional remedies and TB medications.

2.7.5 Physiotherapy:

Physiotherapy can indeed play a valuable role as a complementary therapy in the management of pulmonary tuberculosis (TB). TB affects the lungs primarily, leading to symptoms such as coughing, difficulty breathing, and decreased lung function. Physiotherapy interventions can help address these symptoms and improve overall respiratory function in individuals with TB.(77)

Here are some ways in which physiotherapy can be beneficial in the management of pulmonary TB:

- Breathing Exercises: Physiotherapists can teach patients with TB various breathing exercises aimed at improving lung function, expanding lung capacity, and enhancing ventilation-perfusion matching. These exercises can help reduce breathlessness and improve overall respiratory efficiency.
- Chest Physiotherapy: Techniques such as chest percussion, vibration, and postural drainage can help loosen and mobilize secretions in the lungs, making it easier for patients to clear mucus and phlegm. This can prevent complications such as pneumonia and improve lung function.

- Exercise Prescription: Engaging in appropriate physical activity is important for individuals with TB to maintain muscle strength, cardiovascular fitness, and overall well-being. Physiotherapists can design customized exercise programs tailored to the individual's fitness level and specific needs.
- Education and Support: Physiotherapists can provide education and support to patients with TB, helping them understand the importance of adherence to medication, proper breathing techniques, and lifestyle modifications to optimize respiratory health.
- Pain Management: Some individuals with TB may experience chest pain or discomfort, especially during coughing. Physiotherapists can employ techniques such as manual therapy, therapeutic exercises, and modalities like heat or cold therapy to alleviate pain and improve mobility.

It's essential for physiotherapists to work closely with other healthcare professionals involved in the management of TB, including physicians, nurses, and respiratory therapists, to ensure a comprehensive and coordinated approach to care. By incorporating physiotherapy into the treatment plan, individuals with pulmonary TB can experience improved respiratory function, reduced symptoms, and enhanced quality of life.

Overall, the literature on CAM and pulmonary TB highlights the diversity of non-conventional approaches that individuals may employ to complement or augment conventional medical treatments. While some CAM modalities show promise in improving treatment outcomes, reducing symptoms, and enhancing QOL in TB acquired individuals, rigorous scientific evaluation is needed to validate their efficacy, safety, and integration into comprehensive TB care strategies. Collaborative efforts between conventional healthcare providers, researchers, policymakers, and traditional healers are essential to bridge the gap between traditional and evidence-based approaches to TB management.

2.8 Nutrition and PTB

The relationship between nutrition and pulmonary tuberculosis (TB) is complex and multifaceted, with diet playing a crucial role in both the susceptibility to TB infection and the course of the disease. Adequate nutrition is essential for maintaining a healthy immunity is required to fight against PTB. Conversely, malnutrition can make our body weak that causes increase risk of TB infection by making immune system vulnerable and disease progression. So, a summary of the interplay between nutrition and PTB:

1. **Impact of Malnutrition on TB Susceptibility**:

- Malnutrition, particularly deficiencies in key nutrients such as protein, vitamins (e.g., vitamin A, vitamin D, vitamin E, vitamin C), and minerals (e.g., zinc, iron), can impair immune function and increase susceptibility to TB infection.(86,87)
- Undernourished individuals are prone to acquire active TB disease upon exposure for Mycobacterium tuberculosis (the bacteria that cause TB) compared to those with adequate nutrition.

2. **Nutritional Status and TB Disease Severity**:
    - Malnutrition is associated with more severe TB disease manifestations, including higher bacterial loads, greater extent of lung involvement, and increased risk of complications such as disseminated TB and TB meningitis.
    - Poor nutritional status is also linked to delayed sputum smear conversion, prolonged treatment duration, and higher mortality rates among TB patients.
3. **Impact of TB on Nutritional Status**:
    - Active TB disease can lead to nutritional deficiencies and weight loss through various mechanisms, including decreased appetite, increased metabolic demands, nutrient malabsorption, and systemic inflammation.
    - Pulmonary TB can impair lung function, leading to respiratory symptoms such as coughing, dyspnoea, and reduced exercise tolerance, which can further exacerbate malnutrition.
4. **Nutritional Support in TB Management**:
    - Adequate nutrition is an integral component of TB management, encompassing both prevention and treatment strategies.
    - Nutritional supplementation, including high-protein diets, vitamin and mineral supplementation, and therapeutic feeding programs, may help improve nutritional status and immune function in TB patients. (8)
    - Nutritional support should be integrated into TB care protocols, alongside appropriate anti-TB treatment, to optimize treatment outcomes and reduce the risk of treatment failure, relapse, and mortality.
5. **Public Health Interventions**:
    - Public health interventions aimed at improving nutrition can have a positive impact on TB prevention and control efforts.
    - Socio-economic development initiatives, poverty alleviation programs, food security interventions, and nutrition education campaigns can help address

underlying determinants of malnutrition and reduce the risk of TB transmission and progression.

The relationship between nutrition and pulmonary TB is bidirectional, with malnutrition increasing susceptibility to TB infection and TB disease exacerbating nutritional deficiencies. Addressing malnutrition is essential for TB prevention and management, highlighting the importance of integrating nutritional support into comprehensive TB control programs. By promoting adequate nutrition, policymakers, healthcare providers, and communities can contribute to more effective TB prevention, treatment, and ultimately, TB elimination efforts.

2.9 Yoga and PTB

Yoga, an ancient practice originating from India, has gained recognition worldwide for its potential health benefits, including its role in the management of pulmonary tuberculosis (TB). Integrating Yoga into the care of individuals with pulmonary TB can offer a holistic approach to treatment, addressing physical, psychological, and social aspects of well-being. Here's a detailed exploration of the relationship between Yoga and pulmonary TB:

1. **Physical Benefits**:
    - Yoga involves various physical postures (asanas) and breathing exercises (pranayama) that can improve respiratory function, lung capacity, and overall physical fitness. (92,93)
    - For individuals with pulmonary TB, Yoga asanas can help alleviate symptoms such as chest tightness, cough, and shortness of breath, promoting better respiratory health.
    - Breathing techniques taught in Yoga, such as deep breathing and diaphragmatic breathing, can enhance oxygenation, lung ventilation, and respiratory muscle strength, which are essential for managing pulmonary TB.
2. **Psychological Benefits**:
    - Yoga practices, including meditation and mindfulness techniques, can reduce stress, anxiety, and depression commonly experienced by individuals with pulmonary TB.
    - Mind-body interventions in Yoga promote relaxation, emotional balance, and mental clarity, improving psychological well-being and coping with the challenges of TB diagnosis and treatment.

- Yoga can enhance self-awareness, self-compassion, and resilience, empowering individuals to navigate the psychological impact of TB and foster a positive outlook on their health and recovery.

3. **Immune Function**:
    - Emerging research suggests that Yoga may modulate the immune response, enhancing immune function and promoting immune regulation.
    - Regular Yoga practice has been associated with reduced inflammation, improved immune cell activity, and enhanced immune surveillance, which may contribute to better outcomes in individuals with pulmonary TB by supporting the body's ability to fight infection.
4. **Pulmonary Rehabilitation**:
    - Yoga is increasingly identified as an important factor of pulmonary rehabilitation programs for individuals with chronic respiratory conditions, including TB.
    - Pulmonary rehabilitation incorporating Yoga has showed to enhance exercise tolerance, functional capacity, and QOL in individuals with pulmonary TB, particularly during the recovery phase after completing TB treatment.(94)
5. **Complementary Therapy**:
    - Yoga serves as a complementary therapy alongside conventional TB treatment, enhancing its effectiveness and promoting holistic healing.
    - Integrating Yoga into TB care can improve treatment adherence, symptom management, and overall health outcomes, leading to better recovery and reduced risk of TB recurrence.
6. **Accessibility and Affordability**:
    - One of the advantages of Yoga is its accessibility and affordability, making it suitable for individuals from diverse socio-economic backgrounds and resource-limited settings where access to conventional healthcare services may be limited.
    - Yoga can be practiced in various settings, including healthcare facilities, community centres, and even at home, making it a convenient and sustainable adjunctive therapy for individuals with pulmonary TB.

Yoga offers a holistic approach to managing pulmonary TB, addressing physical, psychological, and social aspects of well-being.

By incorporating Yoga into TB care protocols, healthcare providers can enhance treatment outcomes, improve quality of life, and promote overall well-being in individuals affected by pulmonary TB.

3 Chapter-3: Aim and Objectives

3.1 Aim

To Assess the Effect of Integrated Yoga as an Adjuvant Therapy to Standard Care in Pulmonary Tuberculosis.

3.2 Objectives

3.2.1 Primary Objective

The objective of the present study was to Evaluate the Effect of Integrated Yoga as an Adjuvant Therapy to National Tuberculosis Elimination Programme (NTEP) on Pulmonary Functions in patients with Pulmonary Tuberculosis.

3.2.2 Secondary Objectives

1. To Evaluate the Effect of Integrated Yoga as an Adjuvant Therapy to National Tuberculosis Elimination Programme (NTEP) on assessing the Depression in patients with Pulmonary Tuberculosis.
2. To Evaluate the Effect of Integrated Yoga as an Adjuvant Therapy to National Tuberculosis Elimination Programme (NTEP) on assessing the Health-Related Quality of Life (HRQOL) in patients with Pulmonary Tuberculosis.

3.3 Research Question

Is there any effect of Integrated Yoga as an Adjuvant therapy in Pulmonary Tuberculosis patients on Pulmonary Function Test, Health-Related Quality of Life and Depression under National Tuberculosis Elimination Programme (NTEP)?

3.4 Hypothesis

The Eight weeks of Integrated Yoga as Adjuvant to Standard of Care will enhance Pulmonary function parameters, Quality of life and reduces the Depression in the patients with Pulmonary Tuberculosis.

Null Hypothesis:

The Eight weeks of Integrated Yoga as adjuvant to Standard of Care will not enhance Pulmonary function parameters, Quality of life and will not reduce the Depression in the patients with Pulmonary Tuberculosis.

4 Chapter-4: Methodology

4.1 Participants

Seventy-two newly diagnosed Pulmonary Tuberculosis (PTB) patients who received treatment under NTEP programme were recruited according to inclusion and exclusion criteria.

4.2 Sample size.

Sample size was calculated using nMaster 2.0 software. Which was developed by the Biostatistics Training and Resource Center, Department of Biostatistics, Christian Medical College, Vellore, Tamil Nadu, India. Based on the Forced Expiratory Volume in 1 second (FEV1) as reported in the study conducted by Naveen K Visveswaraya et. al. (2003); (81) reported that an average variance estimated of 0.16 in FEV1. Considering the power of 90% with Alpha error α=0.05. The sample estimated per group is 30. Expecting a dropout rate of 20% during the study. The final sample size per group is estimated as 36 and the overall sample size will be 72.

4.3 Mode of Selection

The selected participants were adults around 18-60 years of age. The participants were given regular medication to the control group and Yoga along with standard care under NTEP to the experimental group. The inclusion and exclusion criterion for selected participants as follows,

4.3.1 Inclusion criteria

- New cases of microbiologically diagnosed and clinically diagnosed Pulmonary Tuberculosis patients who will be receiving treatment under National Tuberculosis Elimination Programme (NTEP).
- Age group of patients between 18-60 years.
- Both Male and Female patients with PTB are included in the study.

4.3.2 Exclusion criteria

- TB With HIV
- Multiple Drug resistance TB(MTB)
- Pulmonary Tuberculosis with HIV
- Extra pulmonary tuberculosis
- Patients with psychosis and delirium
- No recent major surgeries in last 4 months.

- Any form of Yoga practice in last 3 months.
- Severe PTB patients.

4.4 Source and Setting of Participants

Pulmonary Tuberculosis patients visited the Department of Pulmonology undergoing NTEP treatment.

4.4.1 Settings

The study was conducted on Pulmonary tuberculosis patients visiting to Department of Pulmonology and Department of Integrative Medicine at RL Jalappa Hospital and Research Center, Tamaka, Kolar.

4.5 Ethical Clearence:

The study was reviewed by the Institutional Ethical Committee, Faculty of Allied Health and Basic Sciences approved the study (SDUAHER/IEC/MJ/13/22-23) before commencement of the study. Also, study was registered under the Central Trial Registry of India (CTRI/2023/01/049012).

4.5.1 Signed informed consent:

Before commencement of the study, the purpose and complete procedures were clearly explained to the participants and their caretakers. Then written informed consent was obtained voluntarily from each participant. Also clearly explained that, if they were not willing to participate in the study their standard treatment care will not be altered.

4.6 Study Design

It is a Randomized control trial study.

4.7 Study Protocol

Eligible patients were randomized ensuring allocation concealment includes sequentially numbered, opaque, sealed envelopes (SNOSE) technique (95) on admission into two groups by randomly picking the envelope as Group A and Group B by the medical officer/ pulmonologist.

Seventy-two participants were asked to pick the envelope randomly and assigned into two groups, control group and Experimental group based on number inside opaque envelope.

For experimental group, standardize care along with the experimental group participants received 45-minute Yoga session five days a week for eight weeks as intervention. For control group, only the standard of care was given as per the NTEP regimen.

4.7.1 Control Group

The other control group will have normal day to day activities that are used to perform along with the Standardized regular medication under National Tuberculosis Elimination Program (NTEP) i.e., anti-tuberculosis drugs as per weight band in NTEP for 8 weeks. The two groups were given Standardized of care under NTEP.(96)

4.7.1.1 Standard of care Treatment

The National Tuberculosis Elimination Program (NTEP) typically provides guidelines for the treatment of pulmonary tuberculosis (TB) in adult patients based on weight bands to ensure appropriate dosing and optimize treatment outcomes. Here's a detailed explanation of the commonly used TB drugs according to weight bands for adult patients as per NTEP:

Isoniazid (INH):

Adult Dose: 5 mg/kg body weight, up to a maximum of 300 mg.

Frequency: Once daily.

INH is a cornerstone drug in the treatment of TB. It works by inhibiting the synthesis of mycolic acids, essential components of the bacterial cell wall.

Rifampicin (RIF):

Adult Dose: 10 mg/kg body weight, up to a maximum of 600 mg.

Frequency: Once daily.

Rifampicin is another essential first-line drug for TB treatment. It acts by inhibiting DNA-dependent RNA polymerase, thus disrupting bacterial RNA synthesis.

Pyrazinamide (PZA):

Adult Dose: 25-30 mg/kg body weight, up to a maximum of 2 g.

Frequency: Once daily.

Pyrazinamide is included in the initial phase of TB treatment. It works by disrupting the bacterial cell membrane and inhibiting protein synthesis.

Ethambutol (EMB):

Adult Dose: 15-20 mg/kg body weight, up to a maximum of 800 mg.

Frequency: Once daily.

Ethambutol is often included in the initial phase of treatment. It works by inhibiting the synthesis of arabinogalactan, an essential component of the bacterial cell wall.

These drugs are typically provided in fixed-dose combinations (FDCs), where multiple drugs are combined into a single tablet or capsule as shown in the figure-1. (96) This simplifies dosing and improves adherence to the treatment regimen.

Figure-1: NTEP Antituberculosis Drugs chart according to Weight band category.

Weight Category (kg)	Number of Fixed Dose Combinations (FDCs)	
	Intensive Phase	Continuation Phase
	HRZE*	HRE*
	75/150/400/275 (in mg)	75/150/275 (in mg)
25-39	2	2
40-54	3	3
55-69	4	4
70-75	5	5
>75	6	6

*H:Isoniazid, R-Rifampicin, Z:Pyrazinamide, E-Ethambutol

For example, a commonly used FDC for adult patients is the combination of INH, RIF, PZA, and EMB, where the dosages are adjusted according to the patient's weight band. This combination is often provided in different tablet strengths to accommodate varying doses.

It's important for healthcare providers to calculate the appropriate dosage based on the patient's weight and ensure that the patient receives the correct medications and doses throughout the course of treatment. Close monitoring of patients for treatment response and adverse effects is also essential to ensure successful treatment outcomes.

4.7.1.2 National Tuberculosis Elimination Programme (NTEP)

National Tuberculosis Elimination Programme (NTEP) is the public health initiative works as a flagship program under National Health Mission (NHM). It comes under Indian ministry of health and family welfare, Government of India. In the beginning of 2020, the government of India has renamed RNTCP as the NTEP. Central government has committed to attaining a justifiable aim of ending Tuberculosis by 2025, as 5 years before the international targets.

Figure-2: NSP 4 Strategic Pillers

The National Strategic Plan (NSP) 2017-2025, scheme has idea of reaching a "TB free India" with "zero deaths and aim to offer universal access to TB control services such as free nutritional support, free cost, quality of TB diagnosis and treatment throughout the country through government health system". NSP has integrating 4 strategic pillars like Detect-Treat-Prevent-Build as shown in Figure-2. (97)

Program Structure:

The management structure of the tuberculosis program operates through a 4-tier order, starting from the "National level down to the sub-district level". At the national level, Central TB Division, under the Ministry of Health and Family Welfare, leads the program. This division is overseen by the "Deputy Director General - TB (DDG-TB)", who serves as the National Program Manager. Administrative oversight extends to the "Additional Secretary and Director General (NTEP and NACO)", as well as the "Joint Secretary-TB". "National Level Expert Committees and National Institutes for Tuberculosis" provide advisory and supportive functions.

At the state level, "State TB Cell" led by a State TB Officer, manages program activities, while at the district level, the District TB Office, headed by a District TB Officer, oversees operations. The sub-district level activities are coordinated through Tuberculosis Units (TB Units).

Laboratory services are structured in a three-tiered system. "Microscopy and rapid molecular tests" constitute the first tier at service/facility levels. "Intermediate Reference Laboratories (IRL) and Culture and Drug Susceptibility Testing (C&DST) Labs" form the second tier, providing "advanced DST facilities" and support to the first tier. The third tier consists of "National Reference Laboratories, offering quality assurance, certification services for C&DST labs, and coordinating with the WHO Supra National Reference Laboratory Network". Additionally, "Chest Radiography, available at tertiary and secondary healthcare levels", plays a crucial role in screening and clinical diagnosis of Tuberculosis.

The "National TB Elimination Program (NTEP)", established from January 1, 2020, builds upon the advancements made in the "Revised National Tuberculosis Control Program (RNTCP)" since 2016. With the Govt. of India's (GoI) commitment to achieving "END TB targets" ahead of schedule, the program was renamed to reflect its focus on elimination.

Sanjeeva Kumar, Special Secretary of the Ministry of Health and Family Welfare, announced this decision in a letter to all State Chief Secretaries.

NIKSHAY:

NI-KSHAY, short for "Ni" meaning end and "Kshay" for TB, serves as the web-enabled patient management system for TB control within the National Tuberculosis Elimination Programme (NTEP). Developed and managed by the “Central TB Division (CTD)” under the “Govt. of India- Ministry of Health and Family Welfare (GoI-MoHFW)”, in partnership with “National Informatics Centre (NIC) and the World Health Organization's” office for India. (98)

Healthcare workers at different levels, both in the public and private sectors, utilize NI-KSHAY to register TB cases under their care, request various tests from laboratories nationwide, document treatment details, monitor treatment adherence, and facilitate the transfer of cases between healthcare providers. Additionally, it works as “National TB Surveillance System”, enabling the reporting of various surveillance data to the GoI.

4.8 Randomization:

The study involved the screening of 826 Pulmonary TB patients with the help of District Tuberculosis Officers (DTO) and District Health Officers (DHO). After receiving of permission to screen the patient’s monthly basis and recruited the patients. As special permission was obtained to collect the data from PTB patient in the district; out of which 754 were excluded for not meeting the inclusion criteria, leaving 72 eligible patients who agreed to participate. These patients were randomly assigned to either a Yoga group or a control group using the sequentially numbered opaque sealed envelopes (SNOSE) technique.(95) Each envelope, labelled as either group A (control) or group B (experiential/Yoga), was of the same size and had the group assignment written inside. The envelopes for groups A and B were mixed after labelling. During their visit to the Department of Pulmonology, patients were asked to select one opaque sealed envelope as depicted in Figure 3. Thirty-six participants received group A envelopes, while the remaining 36 received group B envelopes. Ultimately, the study was completed by all 72 patients represented in CONSORT flow chart(99) as shown in Figure 4.

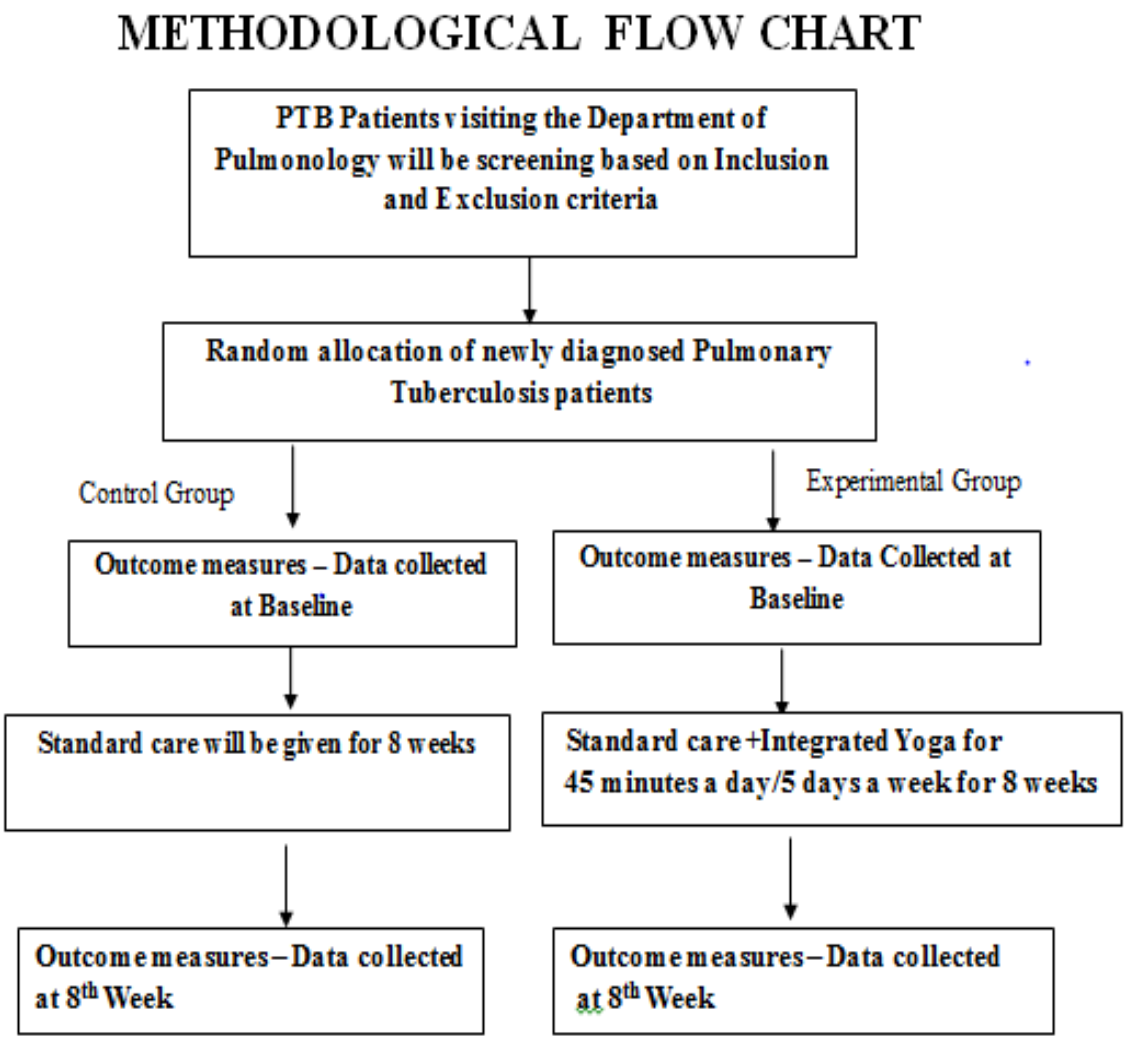


Figure-3: Methodological Procedural Flow chart.

CONSORT Flow Diagram

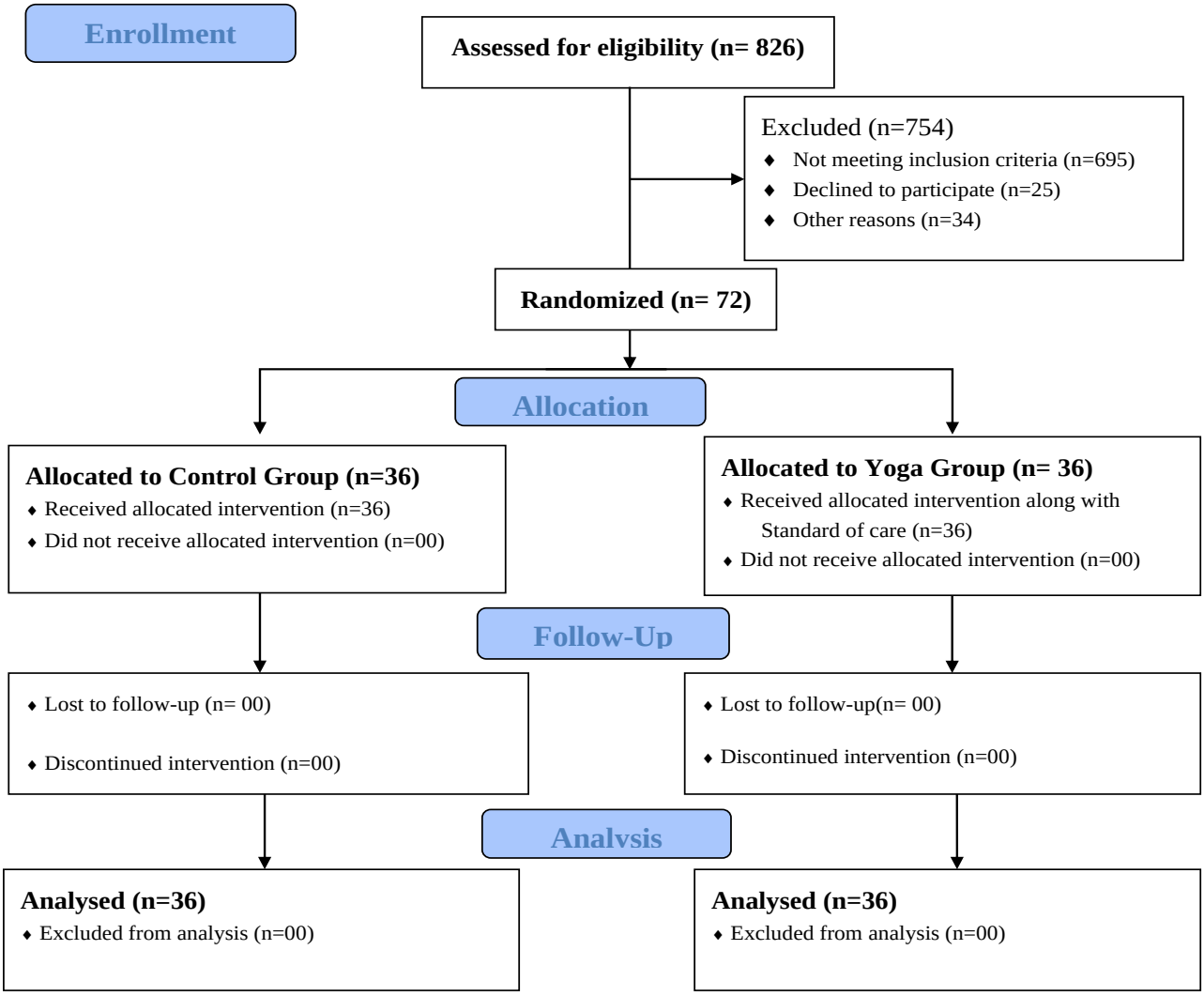


Figure-4: CONSORT Flow Diagram

4.9 Yoga/Study Intervention

Table 4: Yoga Practice Module

SI. No	Name of the practice	Duration
I	**BREATHING EXERCISES**	**06 Minutes**
01	Hands in and out breathing	
02	Hands stretch breathing	
03	Sasankasana breathing (moon pose)	
II	**LOOSENING EXERCISES**	**04 Minutes**
04	Shoulder rotation	
05	Forward and backward bending x 3 rounds	
06	Instant Relaxation Technique	
III	**YOGASANAS/PHYSICAL POSTURES**	**10 Minutes**
07	Ardhakati cakrasana (Lateral arc pose)	
08	Ardha cakrasana (Half wheel pose)	
09	Bhujangasana (Serpent pose)	
10	Deep Relaxation Technique	
IV	**PRANAYAMA**	**15 Minutes**
11	Nadisudhi Pranayama (Alternate nostril breathing)	
12	Bhramari pranayama (Bee breathing)	
13	Nadanusandhan	
V	**RELAXATION**	**10 Minutes**
14	Yoga Nidra (Guided Meditation)/Deep Relaxation Technique	
Total duration		**45 minutes**

Integrated Yoga therapy model is based on the principle that the root of all psychosocial illnesses is in the mind; whenever there is imbalance in the Pancha kosha due to avoidable/unavoidable circumstances will lead to conflict between the emotional level (manomaya Kosa) and wisdom level (Vignanamaya Kosa). The desires such as likes and dislikes at psychological level will alter at the gross levels i.e. in Pranamaya Kosa and Annamaya kosa. Based on the Pancha kosa concept of integrated Yoga model was designed for each level which was beneficial for the patients with different diseases and problems.(100)

The experimental group was given 45 minutes of Yoga practices every day, 5 days in week, 8 weeks of video instructions to the patients along with regular standardize regime under National Tuberculosis Elimination Programme (NTEP) as shown in the figure 1. Initially for 5 sessions Yoga module demonstration was thought to the participants. Then participants were given the Yoga module video in the mobile or storage devices. Once they learn the module, they started practicing every day after the training of 5 days. Every day patients were enquired through tele caller and visiting the participants' home every week for 8 weeks and register/logbook was maintained. The caretakers were encouraged to monitor the participants and inform to the investigator about the compliance. The set of Yoga practices was given as shown in Table 4. The module has been designed and validated by Yoga experts. Yoga module validation has been done in the department under Dr. Patil NJ and Dr. Dhanashree Patil. The Yoga intervention consists of yogic breathing exercise has positive effect (6,19); Loosening Exercise; Asana /physical postures, pranayama plays a crucial role in improving lung functions (14,18); meditation and relaxation in supine posture relieves of stress and anxiety in the patients by making their mind calm.

4.9.1 Breathing Exercises

The detailed explanation of each breathing exercise along with instructions on how to perform them are mentioned below:

1. Hands in and Out Breathing:

- Sit in a restful condition on a floor in a cross-legged posture or on a chair with spinal cord erect and shoulders relaxed.
- Place hands on the knees with palms towards down.
- As you inhale through nose, slowly slide hands up thighs toward hips, lifting chest and opening shoulders.
- At the top of inhalation, hands should be at hips or slightly behind you.
- Exhale through nose, reversing the motion by sliding hands back down thighs toward knees, gently rounding spine and tucking chin toward chest.
- Repeat this movement, coordinating the breath with the motion of hands, for several rounds, focusing on smooth and controlled movements.
- **Advantages:**
    - Helps improve diaphragmatic breathing, which can enhance lung ventilation and oxygenation.

- Promotes relaxation and reduces stress by activating the body's parasympathetic nervous system.
- Enhances awareness of breathing patterns and encourages mindful breathing, which can be beneficial for managing anxiety and promoting overall well-being.(101)

2. Hands Stretch Breathing:

- Sit in a restful condition with spinal cord erect and shoulders at rest position.
- Interlace fingers and extend arms straight out in front of you at shoulder height, palms facing away from you.
- When breath in deeply through nose, lengthen spine, and stretch arms forward, keeping them parallel to the floor.
- Hold the breath for a moment at the end of the inhalation, feeling the expansion in chest and shoulders.
- Exhale slowly through nose as you release the stretch, bringing arms back to sides.
- Repeat this movement, synchronizing the breath with the stretch of arms, for several repetitions, focusing on maintaining smooth and steady breathing.
- **Advantages**:
    - Opens the chest and ribcage, allowing for deeper breathing and improved lung expansion.
    - Stretches the muscles of the upper body, including the shoulders, chest, and upper back, promoting flexibility and mobility.
    - Encourages a sense of openness and vitality, helping to alleviate feelings of tension and stiffness in the upper body.

3. Sasankasana Breathing (Moon Pose):

- Start by kneeling on the floor with knees hip-width apart and toes pointed back.
- Sit back on heels and lengthen spine, keeping shoulders relaxed.
- As you inhale deeply through nose, raise arms overhead, reaching up toward the ceiling with palms facing each other.
- As you exhale, slowly bend forward from hips, keeping spine long, and lower forehead toward the floor.
- Rest arms on the floor in front of you, palms facing down, and relax shoulders.
- Hold this position for a few breaths, feeling a gentle stretch along spine and the back of neck.

- To come out of the pose, slowly inhale and lift torso back up to an upright position, raising arms overhead.
- Exhale as you lower arms back down to sides, returning to the starting position.
- Repeat this sequence, moving smoothly and with awareness of breath, for several rounds, focusing on deepening the stretch with each exhalation.
- These breathing exercises can help improve lung function, increase oxygenation, reduce stress, and promote relaxation. Practice them regularly to experience their full benefits.
- **Advantages:**
  - Stretches the spine, shoulders, and chest, releasing tension and promoting better posture.
  - Encourages deep breathing and relaxation, activating the body's parasympathetic nervous system.
  - Helps calm the mind and reduce stress, fostering a sense of inner peace and tranquillity.
  - Incorporating these breathing exercises into daily routine may have numerous benefits for respiratory health, physical well-being, and mental relaxation. Practicing them regularly can help improve lung function, lowers the tension, and enhance overall QOL.

4.9.2 Loosening Exercise

Here's a detailed explanation of each loosening exercise along with instructions on how to perform them and their benefits:

4. Shoulder Rotation:

- Stand with feet hip-width apart and arms hanging loosely at sides.
- Inhale deeply as you lift shoulders up toward ears, tensing the muscles in shoulders and neck.
- Exhale slowly as you roll shoulders back and down in a smooth, circular motion, squeezing shoulder blades together.
- Continue the shoulder roll, inhaling as you lift shoulders up and exhaling as you roll them back and down.
- Repeat this movement for several rounds, alternating between forward and backward shoulder rotations.

- **Benefits:** Shoulder rotations help to improve flexibility and mobility in the shoulder joints, release tension in the neck and upper back muscles, and promote relaxation.

5. Forward and Backward Bending:

- Stand with the feet hip-width apart and arms hanging loosely at sides.
- Breathe in deeply as raise the arms above the head, reaching up toward the ceiling with palms facing each other.
- Exhale slowly as you bend forward from hips, keeping back straight and reaching hands toward the floor or shins.
- Hold the forward bend for a few breaths, feels a gentle stretch in the back of legs along spine.
- Breathe slowly roll spine back up to standing posture, stacking each vertebra one on top of the other.
- Exhale as you release arms back down to sides.
- Repeat this sequence for several rounds, moving smoothly and with awareness of breath.
- **Benefits:** Forward and backward bending stretches the muscles along the back of the body, including the hamstrings, lower back, and spine. It helps improve flexibility, reduce stiffness, and relieve tension in the back muscles.

6. Instant Relaxation Technique:

- Find a comfortable seated or lying position, with spine straight and arms resting at sides.
- Close eyes and take a few deep breaths, inhaling deeply through nose and exhaling slowly through mouth.
- Bring awareness to body and notice any areas of tension or discomfort.
- Starting from toes, consciously relax each part of body, moving gradually upward toward head.
- As you exhale, imagine releasing any tension or stress from each muscle group, allowing them to become loose, heavy, and relaxed.
- Continue this relaxation technique for several minutes, focusing on deep, rhythmic breathing and letting go of any tension with each exhale.
- **Benefits:** The instant relaxation technique helps to reduce stress, promote a sense of calmness and relaxation, and alleviate physical tension throughout the body. It can be used as a quick and effective way to unwind and recharge during times of stress or anxiety.

- Incorporate these loosening exercises into daily routine to improve flexibility, release tension, and promote relaxation in both the body and mind.

4.9.3 Yogasanas/Physical Postures

7. Ardhakati Cakrasana (Lateral Arc Pose):

- Stand on the feet hip-width apart and arms by the sides.
- Breathe deeply and raise left arm above the head, touching up toward the top as maximum amount.
- Breathe out slowly and gently bend torso to the right, creating a lateral arc shape with body.
- Keep feet firmly planted on the ground and avoid leaning forward or backward.
- Be there in the posture for a few breaths, see the stretch in the left side of the body.
- Inhale as you return to the center, then repeat on the other side.
- **Benefits:** Ardhakati Cakrasana helps stretch and lengthen the muscles along the sides of the body, including the intercostal muscles between the ribs. It improves flexibility, mobility, and posture.

8. Ardha Cakrasana (Half Wheel Pose):

- Standing on the feet with hip-width apart and hands by sides.
- Breathe in deeply and raise hands above the head, reaching up toward the top.
- Breathe out, bend backward from upper back, gently arching spine and lifting chest toward the ceiling.
- Keep feet grounded and engage core muscles to strengthen lower back.
- Be there in the posture for a few breaths, see the stretch in the left side of the body.
- Inhale as you return to an upright position, then repeat if desired.
- **Benefits:** Ardha Cakrasana opens the chest, lungs, and shoulders, improving respiratory function and posture. It also stretches the abdominal muscles and stimulates the digestive organs.

9. Bhujangasana (Serpent Pose):

- Lie on stomach with legs extended and the tops of feet flat on the floor.
- Place palms on the floor under shoulders, with elbows close to body.
- Inhale deeply and press into palms to lift chest off the floor, arching back and looking upward.

- Keep pelvis and lower body grounded while lengthening through spine.
- Hold the pose for a few breaths, focusing on opening the front of body.
- Exhale as you lower chest back down to the floor.
- **Benefits:** Bhujangasana strengthens the spine, opens the chest and lungs, and stretches the abdominal muscles. It can help relieve back pain, improve posture, and stimulate the digestive organs.

10. Deep Relaxation Technique:

- Lie down on back in a comfortable resting position, such as Savasana (Corpse Pose), with arms by sides and legs relaxed.
- Close eyes and take a few deep breaths, allowing body to settle into the floor.
- Bring awareness to every body part, begins with toes and gradually moving upward toward head.
- As you exhale, consciously release any tension or tightness in each muscle group, allowing them to become heavy and relaxed.
- Continue to breathe deeply and slowly, focusing on the sensation of relaxation spreading throughout body.
- Stay in this state of deep relaxation for at least 5-10 minutes, allowing self to rest and rejuvenate.
- **Benefits:** The deep relaxation technique helps to reduce stress, promote a sense of calmness and tranquility, and improve overall well-being. It can also enhance sleep quality, reduce muscle tension, and lower blood pressure.

4.9.4 Pranayama

11. Nadi Shodhana Pranayama (Alternate Nostril Breathing):

- Sit comfortably in a cross-legged position with spine tall and shoulders relaxed.
- Place left hand on left knee in Jnana mudra (index finger and thumb touching) and bring right hand toward face.
- With right hand, use thumb to smoothly close right nostril and breathe deeply through left nostril.
- After inhaling fully, use ring finger or little finger to close left nostril, and release right nostril.
- Exhale completely through right nostril.

- Next, inhale deeply through right nostril.
- After inhaling fully, use thumb to close right nostril and release left nostril.
- Exhale completely through left nostril.
- Continue this pattern of alternate nostril breathing for several rounds, moving smoothly, and coordinating the breath with the movement of fingers.
- **Benefits:** Nadi Shodhana Pranayama helps steady the flow of prana in body, relaxes the mind, lower the stress and tension, improve concentration, enhance respiratory function.

12. Bhramari Pranayama (Bee Breathing):

- Sit comfortably in a cross-legged position or on a chair with spine erect and shoulders relaxed.
- Close eyes and take a few deep breaths to relax body and mind.
- Place index fingers on ears, pressing the cartilage to close ear openings.
- Inhale deeply through nose.
- Exhale slowly and steadily, making a soft humming sound like a bee as you do so.
- Feel the vibration of the sound resonating in head and chest.
- Continue to exhale with the humming sound for several rounds, focusing on the sensation and vibration.
- After completing the rounds, release fingers from ears and take a few moments to observe any sensations in body and mind.
- **Benefits:** Bhramari Pranayama helps calm the nervous system, reduce stress and anxiety, alleviate tension in the head and neck, improve concentration, and induce a state of relaxation and tranquillity.

13. Nadanusandhan:

- Sit comfortably in a cross-legged position or on a chair with spine tall and shoulders relaxed.
- Close eyes and take a few deep breaths to center self.
- Bring awareness to breath, observing the natural rhythm of inhalation and exhalation.
- As you breathe in, mentally repeat the sound "So" (pronounced as "soo") silently toself.
- As you breathe out, mentally repeat the sound "Hum" (pronounced as "hoom") silently to self.
- Continue to focus on the sound of breath, silently repeating "So" on inhalation and "Hum" on breath out.

- Mind lose concentration, then smoothly come back to the proper breathing pattern and the repetition of the sounds.
- Practice Nadanusandhan for several minutes, allowing self to enter a state of deep relaxation and inner stillness.
- **Benefits:** Nadanusandhan helps quiet the mind, deepen concentration, enhance self-awareness, promote mental clarity, and cultivate a sense of inner peace and harmony.
- Incorporate these pranayama techniques into PTB patients' daily practice to experience their full benefits for physical, mental, and emotional well-being. Practice them with mindfulness and awareness, gradually increasing the duration and intensity.

4.9.5 Relaxation

14. Yoga Nidra (Guided Meditation):

- Find a comfortable lying position on back, such as Savasana (Corpse Pose), with arms by sides and legs relaxed.
- Close eyes and take a few deep breaths to relax body and mind.
- Begin to bring awareness to all parts of the body, starting with toes and gradually moving upward toward top of the body.
- As you focus on each body part, consciously relax, and release any tension or tightness you may be holding.
- Once you have relaxed entire body, shift attention to breath, observing the natural rhythm of inhalation and exhalation.
- Now, imagine self in a peaceful and serene environment, such as a beach, forest, or mountain.
- Follow the guidance of a recorded Yoga Nidra meditation or a teacher, who will lead you through a series of visualizations, affirmations, and body scans to induce a state of deep relaxation and inner awareness.
- Allow yourself to surrender to the experience, letting go of any thoughts, worries, or distractions that may arise.
- After completing the guided meditation, slowly bring awareness back to surroundings, gently wiggle fingers and toes, and gradually open eyes.

- **Benefits:** Yoga Nidra promotes deep relaxation, reduces stress and anxiety, improves sleep quality, enhances self-awareness and introspection, and cultivates a sense of inner peace and well-being.

15. **Deep Relaxation Technique:**
    - Find a comfortable lying position on back, such as Savasana (Corpse Pose), with arms by sides and legs relaxed.
    - Close eyes and take a few deep breaths to center self and relax body.
    - Bring awareness to each part of body, starting from toes and gradually moving upward toward head.
    - As you focus on each body part, consciously relax, and release any tension or tightness you may be holding.
    - Imagine each muscle group becoming loose, heavy, and completely relaxed with each exhalation.
    - Continue to breathe deeply and slowly, allowing self to sink deeper into a state of relaxation with each breath.
    - Let go of any thoughts, worries, or distractions that may arise, and simply surrender to the experience of deep relaxation.
    - Stay in this state of relaxation for at least 5-10 minutes, allowing self to rest and rejuvenate.
    - When you are ready to return to wakefulness, slowly bring awareness back to surroundings, gently wiggle fingers and toes, and gradually open eyes.
    - **Benefits:** The deep relaxation technique helps reduce muscle tension, lower blood pressure, calm the nervous system, improve sleep quality, and promote overall well-being and relaxation.

4.10 Assessments

4.10.1 Primary Variable

4.10.1.1 Pulmonary Function Tests (PFT)

Pulmonary Function Tests (PFT's) are group of non-invasive tests that shows the how well your lungs work, how lungs take in and exhale air, and how efficiently they transfer oxygen into blood. The PFT's usually measure lung volume, lung capacity, rates of flow, and gas exchange. PFT's useful in measuring the functional status of the respiratory system in both

physiological and pathophysiological condition. (102) It is based on the volume of air breathed in and breathed out in a normal breathing condition and forced breathing condition. It is usually carried out through Spirometry. The lung's function depends / varies with Height, Age, Gender, and body position.

4.10.1.2 Spirometry

Spirometry is a device used for a physiological test which measures the ability to inhale and exhale air in relation to time and estimate lung size. The main results of spirometry are forced vital capacity (FVC) - patient is exhaling at maximal speed and effort and forced expiratory volume (FEV) - expiratory volume in t seconds from a position of full inspiration. The procedure of spirometry has 3 phases: 1) maximal inspiration; 2) a "blast" of exhalation; 3) continued complete exhalation to the end of the test. Normal findings of spirometry are FEV/FVC ratio of greater than 0.70 and both FEV and FVC above 80% of predicted value.(102) PFT of sputum positive patients will be done after patients turns sputum negative after two weeks of treatment. The baseline of the PFT will be at baseline before start of the treatment, and then post data was collected at 8th week of the study as shown in the table 6.

4.10.1.3 Strategy for Revitalization of National Tuberculosis Elimination Program (NTEP) Services in the COVID-19 and Post-COVID-19 Situation, According to Guidelines from the Ministry of Health and Family Welfare (MoHFW) and Central TB Division: (19)

Diagnostic Algorithm:

- "Implementation of bidirectional screening for TB and COVID-19: Screening all diagnosed TB patients for COVID-19 and screening all COVID-19-positive patients for TB.
- TB screening and testing for all suspected cases of Influenza-Like Illness (ILI), Severe Acute Respiratory Infection (SARI), and COVID-19 in all designated COVID-19 zones.
- Integration of TB-COVID laboratory services, including pre-treatment evaluations for drug-resistant and drug-sensitive TB, to optimize available technologies.
- Restoration of diagnostic capacity currently diverted for COVID-19 testing by providing additional equipment.
- Establishment of referral pathways to COVID Care Centers, COVID Health Centers, and COVID-dedicated hospitals.

- Introduction of lung health services, providing diagnostic services for all priority acute/chronic respiratory diseases with the support of a free diagnostic initiative.
- Biomedical Waste Management (BMWM): Ensuring proper disposal of waste according to standard biomedical waste management guidelines".

4.10.1.4 General Guidance (Following Rational of PPE Standards as per GoI):

- "Adherence to standard precautions at all times.
- Personal Protective Equipment (PPE) should complement basic preventive public health measures like hand hygiene and respiratory etiquette, which should always be observed.
- Compliance with the prescribed protocol for disposing of PPEs as outlined in the infection prevention and control guidelines available on the MoHFW website".

Guidelines for Different Categories of Personnel:

- "Doctors' Chambers/Physical Consultation: Use of triple-layer medical masks and latex examination gloves; avoidance of aerosol-generating procedures.
- Handling of Specimens: Use of disposable N95 respirators (masks), disposable aprons/surgical gowns/normal aprons covered with a plastic sheet, gloves (vinyl or latex), and disposable headgear (cap).
- Outreach Staff: Use of triple-layer medical masks and latex examination gloves.
- Radiodiagnosis/Pharmacy Counter/Stores/Laundry Help Desk/Registration Counter: Use of triple-layer medical masks and latex examination gloves".

4.10.2 Secondary Variables:

4.10.2.1 Hamilton Depression Rating Scale (HADS)

Psychological stress refers to abnormal condition due to mental stress/strain. In the present scenario we are concentrating on depression, as it is a one of the major factors that can be often seen in tuberculosis patients. Here we are observing comorbid depression in TB patient, and it was addressed through the Hamilton Depression Rating Scale (HDRS) questionnaire.

The Hamilton Depression Rating Scale (HDRS), commonly referred to as the Ham-D, is a frequently used tool for assessing depression by clinicians and time taken to complete the interview the each patient was around 15-20 minutes. Initially comprising 17 items (HDRS17), it evaluates symptoms experienced within the preceding week. While it was originally intended for completion following an unstructured clinical interview, semi-structured interview guides are now accessible. Originally crafted for use with hospitalized patients, the scale focuses

primarily on melancholic and physical manifestations of depression. The data will be collected at baseline and end of the study. (103)

The range of score for HDRS as follows,

0-7_____These considered as normal

8-16_____ Mild depression

17-23_____ Moderate depression

Over 24_____ Severe depression

The maximum score being 52 on the 17-point scale.

Reliability co-efficient for the HDRS include correlation between each item and total score ranging from 0.31-0.68, split half reliability from 0.86-093.

4.10.2.2 WHO BREF- Quality of Life

Health-related quality of life (HRQOL) encompasses an individual's overall quality of life, reflecting the functional impact of illness and its subsequent treatment, as perceived by the patient. The assessment of HRQOL was conducted using the WHOQOL-BREF questionnaire at both the baseline and the end of the 8th week of the study. Time taken to complete the WHOQOL-BREF questionnaire was around 15(±5) minutes. The WHOQOL-BREF questionnaire comprises 26 items, providing insights into 4 broad domains as Physical health, psychological health, Social Relationships, and Environment.(104)

Research indicates that patients with Pulmonary Tuberculosis (PTB) often experience significant impairments in HRQOL.(105) The observations highlight the importance of utilizing the HRQOL-BREF assessment as an additional outcome measure for PTB patients undergoing treatment as per National Tuberculosis Elimination Program (NTEP) in India.

5 Chapter-5: Data Extraction and Analysis of data

5.1 Data collection:

Pulmonary tuberculosis patients' samples were collected as per NTEP norms in RL Jalappa Hospital and Research Centre (RLJH& RC) is a nodal DOT Centre for TB. The pulmonary parameters like FEV1 and FVC, body weight/BMI, sputum test, sputum Culture, chest X-ray, health related quality of life assessment, depression assessment and patient's compliance/recovery rate was collected for better understanding of the changes before and after intervention. To ensure the independent proof of the observations or investigators bias persons who are not involved in the study were used for assessing or monitoring the data. For the primary objective, which includes Pulmonary Function Tests (PFT), the generated reports were overseen by a Pulmonologist who was independent of the study team. In the case of secondary objectives, such as administering questionnaires, an individual not affiliated with the research team conducted the process. Additionally, to mitigate potential bias from investigators, 10% of participant questionnaires were cross-checked by an individual with a designation no lower than Assistant Professor, who was not part of the research team.

The type of method/Questionnaire used in the collection of data as shown in the Table-5 and outcome measures was measured in the base line, and 8th week as shown in the Table-6.

Table 5: List of parameters assessed and its methods.

Parameters for Assessment	**Method/Questionnaire used**
FEV1(Liters) & FVC (Liters)	Best of three exhalations on spirometry
Health Related Quality of Life	WHOQOL-BREF Questionnaire
Depression	The Hamilton Depression Rating Scale (HDRS) Questionnaire

Table 6: Timeline of outcome measures

Outcome measures	**Baseline**	**8th week**
Forced Vital Capacity (FVC)	✓	✓
Forced Expiratory Volume in the first second (FEV1)	✓	✓
Ratio of FEV1/FVC	✓	✓
Health related Quality of Life (HRQOL)	✓	✓
The Hamilton Depression Rating Scale (HDRS)	✓	✓

Pulmonary Function Test:

The RMS Helios 401 Spirometry device was utilized to conduct a physiological test aimed at measuring the ability to inhale and exhale air over a period of time, while also estimating lung volumes and capacities. The key outcomes of spirometry include forced vital capacity (FVC), indicating the maximum amount of air exhaled with maximum effort, and forced expiratory volume (FEV), which denotes the volume of air exhaled within a specific time frame following a full inhalation. The spirometry procedure comprises three phases: 1) maximal inhalation; 2) a vigorous exhalation or a "blast" exhalation; 3) sustained complete exhalation until the end of the test. Normal spirometry results typically exhibit an FEV/FVC ratio exceeding 0.70, with both FEV and FVC values surpassing 80% of the predicted value. The pulmonary function test (PFT) was conducted initially as a baseline assessment, with post-data collected at the 8th week of the study, as illustrated in Table 6.

Hamilton Depression Rating Scale:

The study employed validated psychological assessments to measure depression using the Hamilton Depression Rating Scale (HDRS), a reliable and valid tool. (106) HDRS consists of 17 items with scores ranging between 0-52 that measure the different elements of depression and were administered to gather quantitative data on the severity of depressive symptoms.(107) Data was collected at the baseline and the 8th week. These assessments provided a comprehensive view of the participants' mental health status. Dairy for attendance was maintained to ensure adherence to treatment for both groups; Patients below 90% attendance were not considered for final analysis. There was no attrition found.

Health Related Quality of Life:

The WHOQOL-BREF, a Health-Related Quality of Life questionnaire developed by the World Health Organization, was administered by an independent individual not associated with the study. Baseline data was collected both before and after the intervention, during the eighth week. The WHOQOL-BREF questionnaire consists of 26 items that assess four main domains: Physical health, psychological health, Social Relationships, and Environment. (104) The HRQOL in PTB shows there is a significantly impaired in the patient and observations support the utility of HRQOL-BREF assessment as an adjunct outcome measure for patients treated under the RNTCP in India. (108)

Data extraction:

The data was extracted using standard protocols and techniques as per the mentioned norms. Pulmonary Function tests were performed as per the standard procedure in the presence of a Pulmonologist. Maximum care was taken to avoid the contamination of the disease. The Psychological questionnaires data such as Depression was assessed by the physician not involved in the study and quality of life questionnaires were assessed by the investigator and 10% was assessed the person not involved in the study to avoid the investigator bias. All the details were cross-checked to ensure the authenticity and response of the data collected including all forms. The data was entered into the excel sheet in the standard format for the data analysis.

5.2 Data analysis:

Collected data was coded and entered an excel database. Descriptive Statistical analysis was carried out using SPSS software Windows Version 23.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp). Normality was checked using Shapiro-Wilk test and data were found normally distributed. We expressed data in terms of mean ± standard deviation and effect of intervention was analysed using paired t-test for within group analysis. The between group analysis was done using independent t-test. Results on continuous measurements like pulmonary function test were presented as mean ± SD (MinMax) and results on categorical measurements were presented in number (%) and 95% CI. Significance will be assessed at 5% level of significance. P value $P < 0.05$ was statistically significant.

6 Chapter-6: Results

6.1 Study Profile

The Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corporation USA). The Shapiro-Wilk test showed that data follows the normal distribution. Data was analysed for both descriptive and parametric tests. The descriptive analysis used for age, gender, marital status, education, habitat, and socio-economic status (Table-4).

6.2 Demographic Characteristics

Among the 72 participants, the average age was 45 years with a standard deviation of ±10.04 for males and 45.95 years with a standard deviation of ±10.63 for females. Out of the participants, 60 were married, while 12 were unmarried. The proportion of female PTB patients 20(27.77%) was lower than that of males 52(72.22%), which can be attributed to the higher incidence of TB in men in India as showed in Table 7 and Figure-5 & 6. Various epidemiological factors and inherent biological susceptibility in men contribute to this difference, supported by multiple studies indicating that women tend to report fewer cases of TB compared to men. (109)

Table-7: Demographic Data representation

SI. NO	Baseline Characteristics	All patients (n=72) Number (%)	Control (n=36) No. (%)	Yoga (n=36) No. (%)
1	Gender	Male-52(72.22%)	24(67%)	28 (78%)
		Female-20(27.77%)	12 (33%)	8 (22%)
2	Age (Mean, SD)	Male-45±10.04	46.54±10.75	45.21±9.74
		Female-45.95±10.63	46.83±9.47	44.62±13.35
3	Marital Status	Married- 60 (83.3%)	32 (89%)	28 (78%)
		Unmarried-12(16.7%)	4 (11%)	8 (22%)
4	Education	Uneducated-20(27.8%)	13 (36%)	7 (19%)
		Primary School-12(16.7%)	7 (19%)	5 (14%)
		Middle School-12(16.7%)	8 (22%)	4 (11%)
		High School-16(22.2%)	7 (19%)	9 (25%)
		Pre-University-6(8.3%)	0 (0%)	6 (17%)
		Graduation&above-6 (8.3%)	1 (3%)	5 (14%)

5	Habitat	Rural-46(63.9%)	22 (61%)	24 (67%)
		Urban-8(11.1%)	4 (11%)	4 (11%)
		Semi-urban-18(25.0%)	10 (28%)	8 (22%)
6	Socio-economic Status	Low/Poor Class -67(93.1%)	35 (97%)	32 (89%)
		Middle class -5(6.9%)	1 (3%)	4 (11%)
7	Religion	Hindu-60(83.3%)	29 (81%)	31 (86%)
		Muslim-12(16.7%)	7 (19%)	5 (14%)
8	Diet	Vegetarian-2(2.77%)	1 (3%)	1 (3%)
		Mixed-70(97.22%)	35 (97%)	35 (97%)
9	Smoking	Non-Smokers-26(36.11%)	14 (39%)	12 (33%)
		Smokers-46(63.88%)	22 (62%)	24 (67%)
10	Alcoholics	Non-Alcoholic-36(50%)	20 (55%)	16 (45%)
		Alcoholic-36(50%)	17 (47%)	19 (53%)

SD- Standard Deviation; No-Number of patients; % -Percentage

Figure-5: Showing the Gender distribution in the Groups:

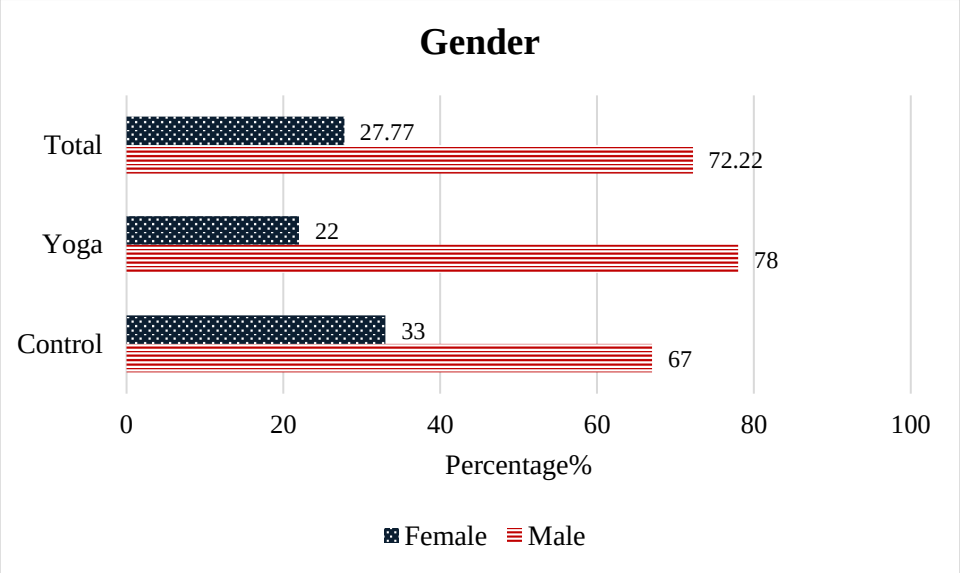
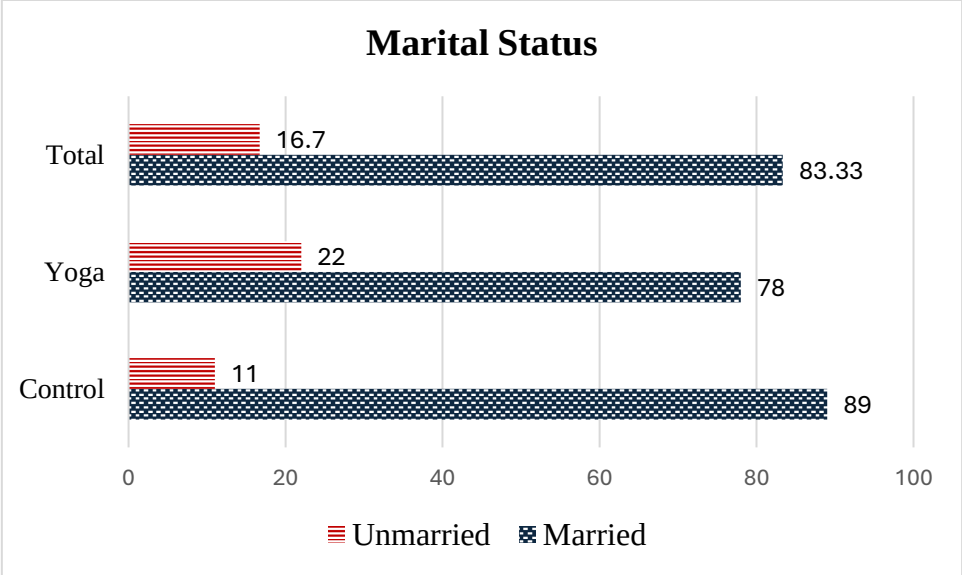


Figure-6: Showing the Marital Status in the Groups:



The demographic data of educational status shows that patients who participated in the study were uneducated or less educated as illiterates were 20(27.8%), remaining lower primary 12(16.7%), middle school 12(16.7%) and high school 16(22.2%) were more in number. Graduation and above were 6% of the total population of study participants as shown in Figure below. Most of them living in rural areas (66%), followed by semi-urban areas (25%), and lastly urban areas (11.1%) as shown in the Figure-7 & 8.

Figure-7: Showing the Education Status in the Groups:

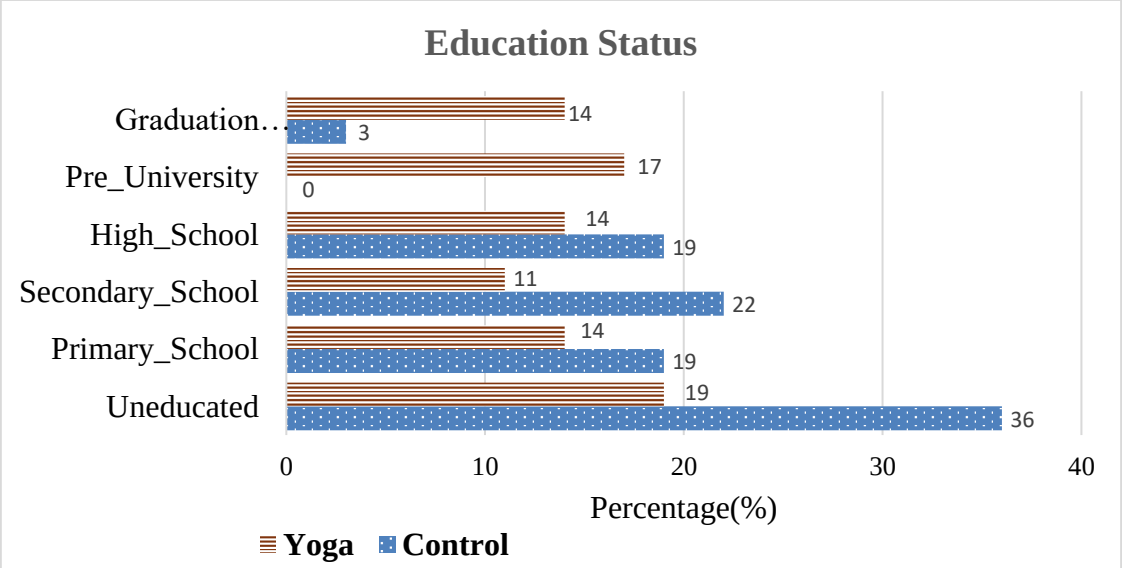
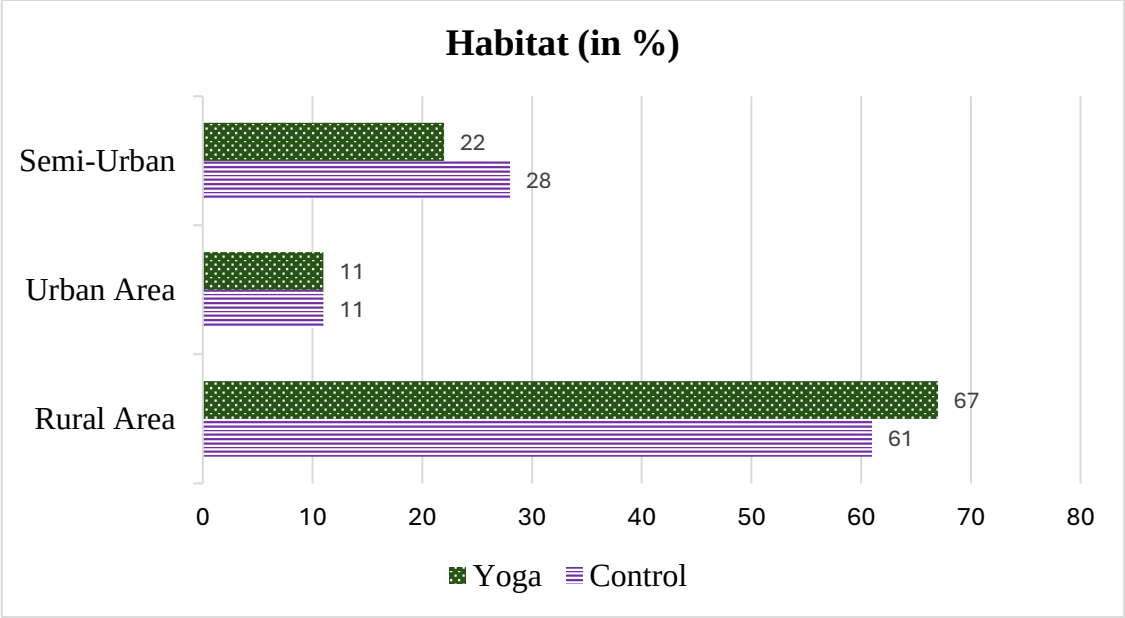


Figure-8: Showing the Habitat distribution in the Groups:



When we discuss about their socio-economic status 93.1% were very poor and only 7% were middle class and none were found in the rich class. When we see their religion 89.3% of affected were Hindus and 16.7% were Muslim patients participated in the study. As we observe their diet pattern maximum were mixed diet followers (97.22%) and very few were vegetarian diet followers (2.77%) in the study as shown in Figures- 9,10 and 11.

Figure-9: Showing the Socio-Economic Status in the Groups:

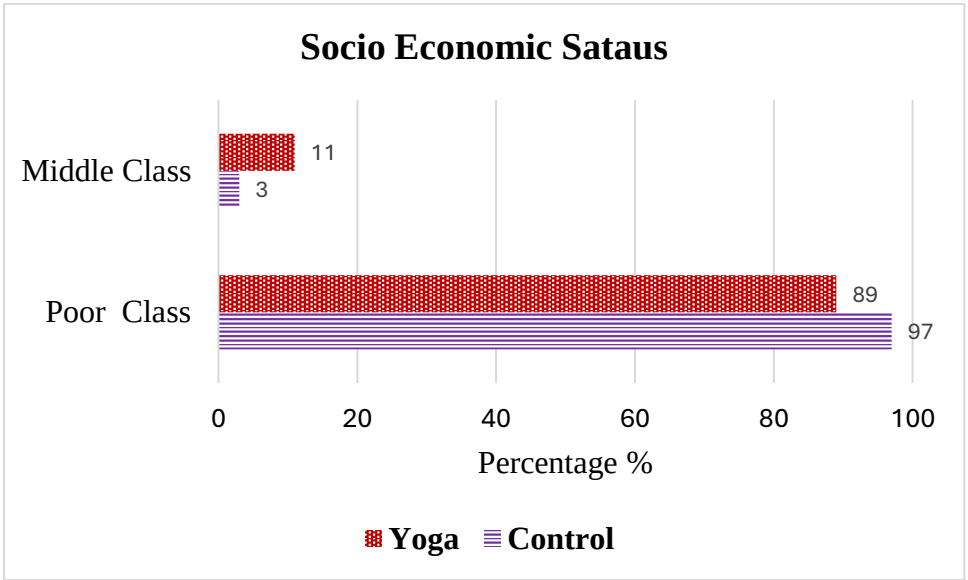


Figure-10: Showing the Religion distribution in the Groups:

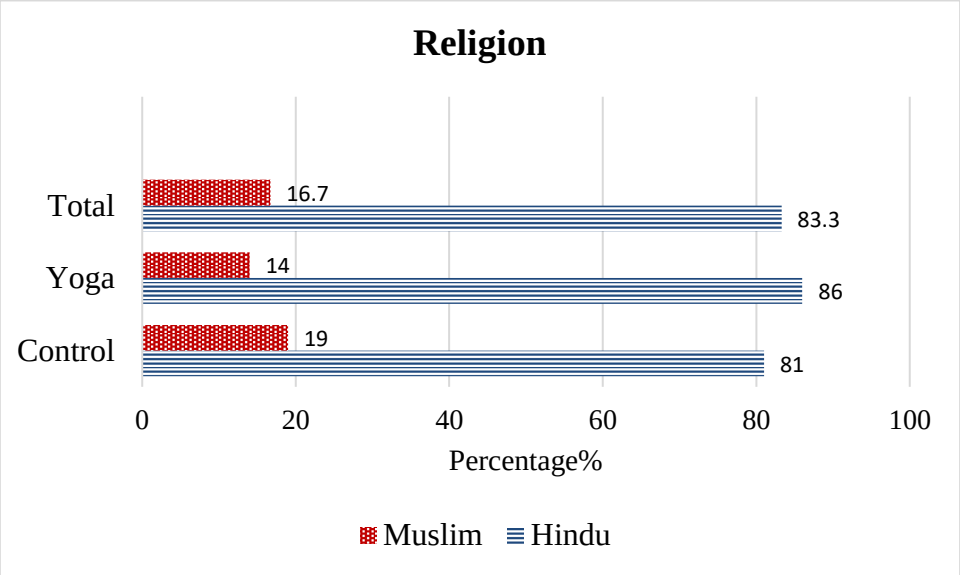
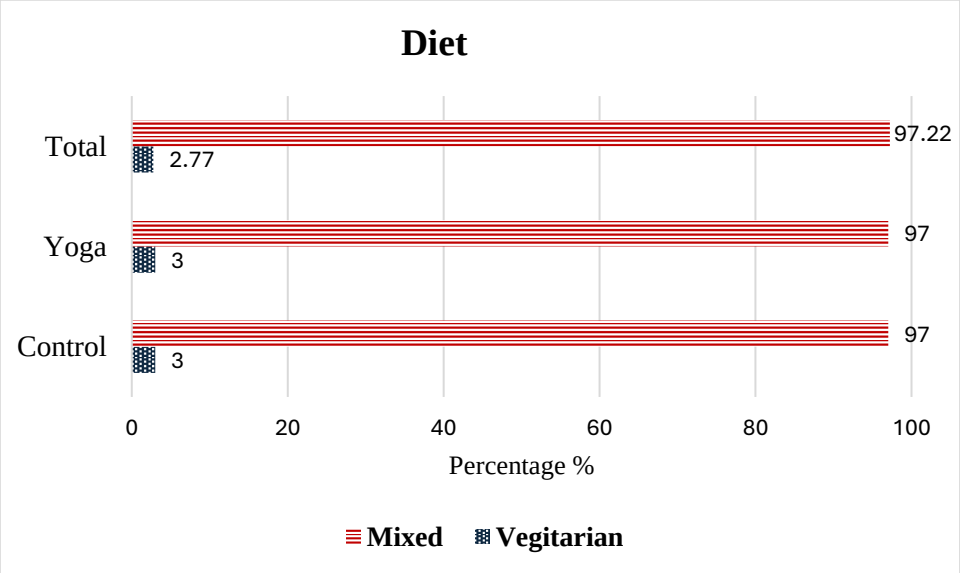


Figure-11: Showing the Diet Pattern in the Groups:



As per the smoking history is concerned, most of them were smokers (63.88%) for long time and very few were non-smokers (36.11%). Interestingly, 50% of the patients were alcoholics and remaining 50% were non-alcoholics as shown in the Figure12,13.

Figure-12: Showing the Smoking distribution in the Groups:

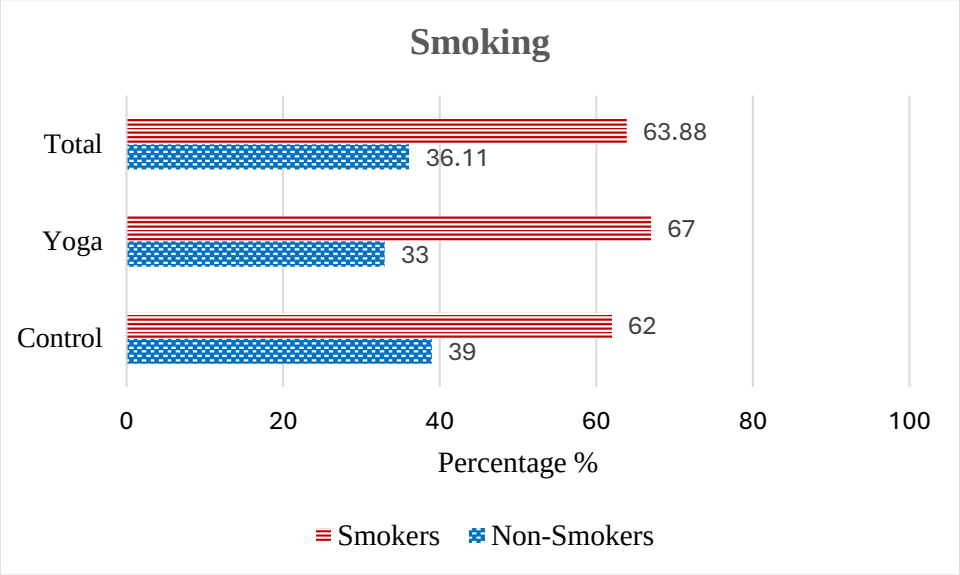
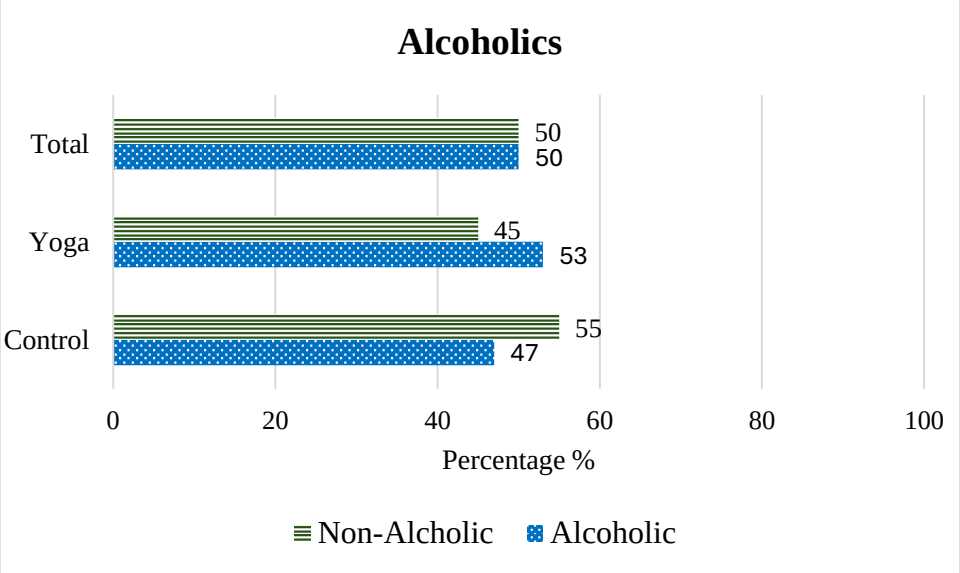


Figure-13: Showing the Alcoholic distribution in the Groups:



6.3 Pulmonary Assessment- PFT

6.3.1 Within Group (Pre-Post) Comparison

Paired t-test was used to analysed within-group comparison. The FEV1 score at baseline was 1.32±0.4 (mean ±standard deviation) and improved after 8 weeks in control group to 1.44±0.4 with effect size of 0.2951. Similarly, The FEV1 score of Yoga group at baseline was 1.36±0.42 (mean ±standard deviation) and improved after 8 weeks of Yoga to 2.05±0.39 with effect size of 1.67. The Yoga group showed an improvement in FEV1, FVC and % FEV1/FVC scores compared to baseline to 8th week, which were statistically significant with $p < 0.0013$, $p < 0.001$ and $p < 0.001$ effect size 0.29, 0.45 and 0.91 (as shown in Table 3). Similarly in the Control Group showed significant improvement in FEV1 and FVC but not in terms of the ratio of % FEV1/FVC values (as shown in Table 8 and Figure-14).

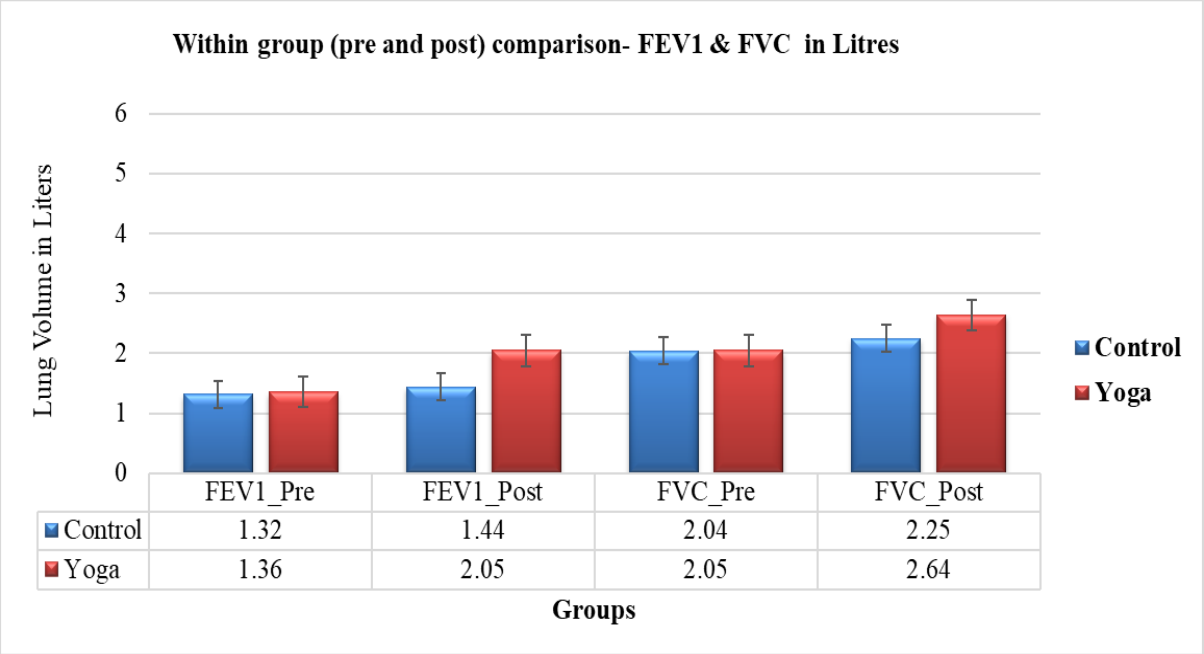
Table- 8: Within Group (Pre-Post) Comparison of FEV1, and FVC:

Parameters	**Mean±SD (PRE)**	**Mean±SD (POST)**	**P (within groups)**	**Effect size (ES)**
Control Group-FEV1	1.32±0.4	1.44±0.4	**0.0013***	0.2951
Yoga Group-FEV1	1.36±0.42	2.05±0.39	**0.001***	1.67
Control Group-FVC	2.04±0.47	2.25±0.34	**0.001***	0.4563
Yoga Group-FVC	2.05±0.49	2.64±0.34	**0.001***	1.3806
Control Group- % FEV1/FVC	81.25±16.07	85.25±17.63	0.085	0.2369
Yoga Group-% FEV1/FVC	81.44±17.01	95.80±14.15	**0.001***	0.9178

Within group (pre and post) comparison; *p<0.05-significant; SD- Standard Deviation; %-Percentage.

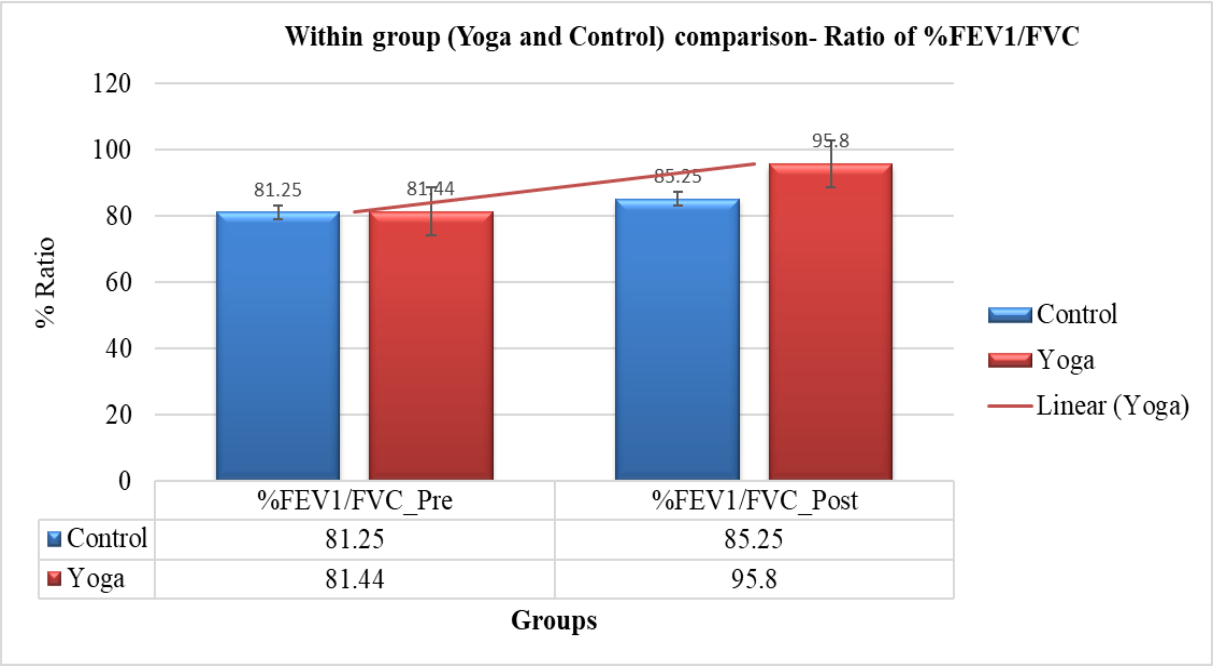
The FVC score at baseline was 2.04±0.47 (mean ±standard deviation) and improved after 8 weeks in control group to 2.25±0.34 with effect size of 0.45. Similarly, The FVC score of Yoga group at baseline was 2.05±0.49 (mean ±standard deviation) and improved after 8 weeks of Yoga to 2.64±0.34 with effect size of 1.38. The value of FVC is statistically significant at 0.001.

Figure-14: Within Group (Pre-Post) Comparison of FEV1, FVC:



FEV1-Pre- Forced Expiratory Volume in 1 second at baseline; FEV1-Post- Forced Expiratory Volume in 1 second after 8 weeks; FVC_Pre- Forced Vital Capacity at baseline; FVC_Post- Forced Vital Capacity after 8 weeks.

Figure-15: Within Group (Pre-Post) Comparison of %FEV1/FVC:



In case Control group, ratio of %FEV1/FVC at baseline was 81.25±16.07 and after 8 weeks changed to 85.25±17.63 with effect size of 0.236. Same way in the Yoga group, the ratio of %FEV1/FVC at baseline was 81.44±17.01 improved to 95.80±14.15 after 8 weeks of Yoga with effect size of 0.917. The ratio of %FEV1/FVC is statistically significant with P=0.001 as shown in Figure-15.

6.3.2 Between-group (Yoga vs Control) Comparison

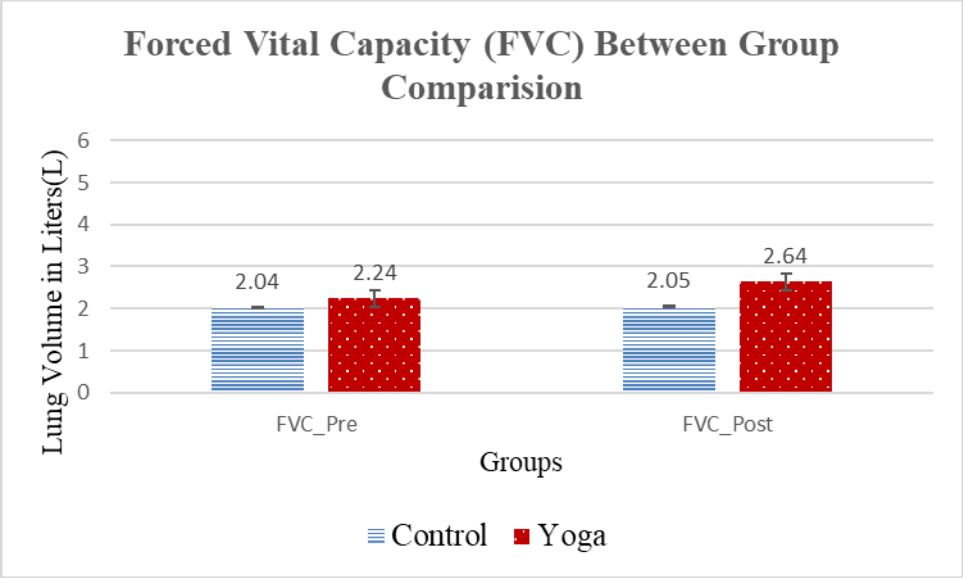
Independent t-test was used to analyse between (Yoga and Control) comparison, the value of FVC at the baseline in control group was 2.04±0.47 (Mean± Standard Deviation) and in Yoga group was 2.05±0.49 which showed insignificant difference in pulmonary function scores at the baseline with the p value 0.955. There was an improvement in (2.24± 0.41 and 2.64± 0.34) the pulmonary function scores after eight weeks of Yoga intervention which was found statistically significant with P value less than 0.001 as shown in the Table-9 and Figure-16,17.

Table-9: Between groups (Yoga vs. Control) comparison:

Pulmonary Function Test **Parameters**	**Mean ± SD (Control)**	**Mean ± SD (Yoga)**	**P (between Groups)**	**Significant difference**
FVC_ Pre	2.04±0.47	2.05±0.49	0.9551	No
FVC_ Post	2.24± 0.41	2.64± 0.34	**<0.001***	**Yes**
FEV1_Pre	1.32±0.4	1.36±0.42	0.9641	No
FEV1_Post	1.44±0.4	2.05±0.39	**<0.001***	**Yes**
%FEV1/FVC_ Pre	81.25±16.07	81.44±17.01	0.8969	No
%FEV1/FVC_ Post	85.25±17.63	95.80±14.15	**0.01***	**Yes**

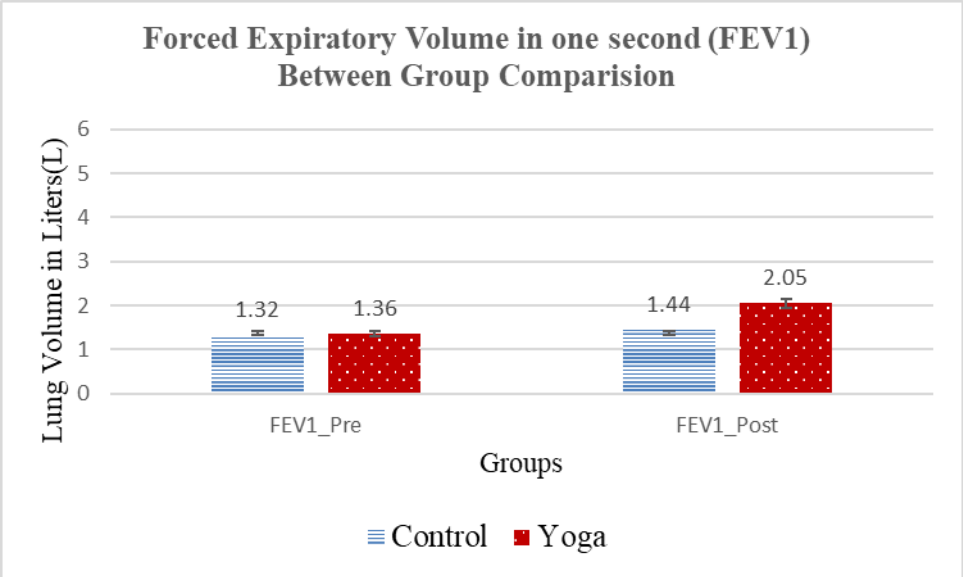
*p<0.05-significant; Pre_ DEP - Depression at Baseline; Post_ DEP - Depression after Intervention; SD-Standard Deviation.

Figure-16: Between Group (Pre vs. Post) Comparison of FVC



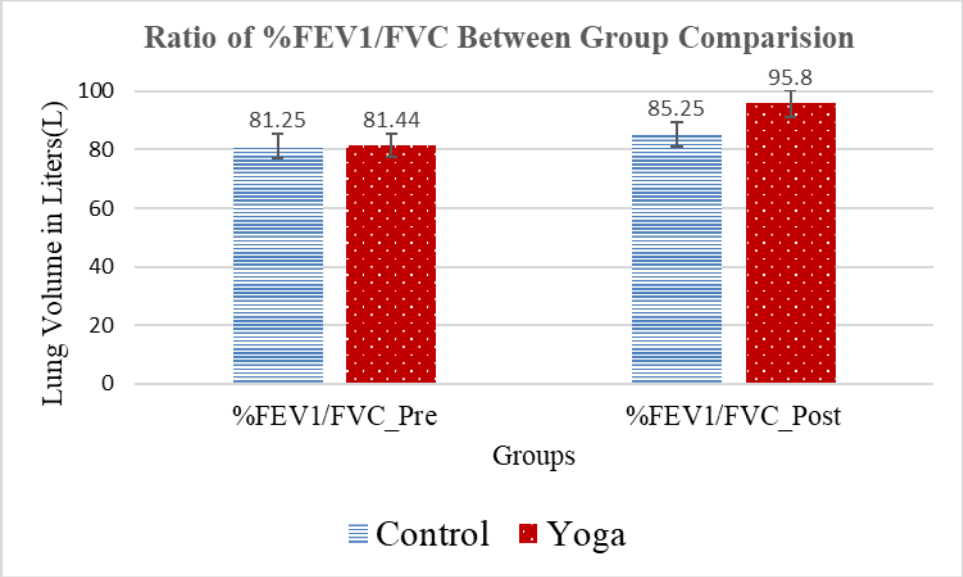
Similarly, the value of FEV1 at baseline in control and Yoga groups were 1.32±0.4 and 1.36±0.42 which were found to be statistically insignificant with the p value 0.964. There was an improvement in (1.44±0.4 and 2.05±0.39) the pulmonary function scores after eight weeks of Yoga intervention which was found statistically significant with P value less than 0.001 as shown in Figure-17.

Figure-17: Between Group (Pre vs. Post) Comparison of FEV1:



In the same way ratio of %FEV1/FVC at baseline in control and Yoga groups were 81.25±16.07 and 81.44±17.01 which were found to be statistically insignificant with the p value 0.896. There was an improvement in (85.25±17.63 and 95.80±14.15) the pulmonary function scores after eight weeks of Yoga intervention which was found statistically significant with P value less than 0.01 as represented in Figure-18.

Figure-18: Between Group (Pre vs. Post) Comparison of ration of %FEV1/FVC



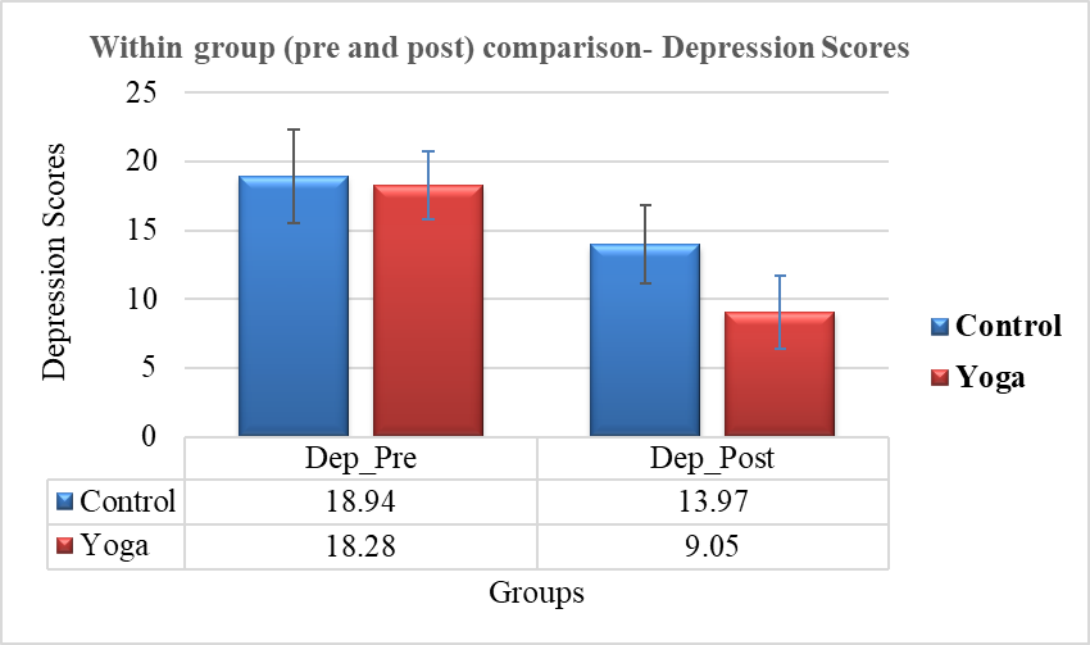
6.4 Hamilton Depression Rating Scale (HDRS)

6.4.1 Within Group (Pre-Post) Comparison

Paired t-test was used to analysed within-group comparison. The control group showed a reduction in depressive scores from 18.94±3.38 (M:SD at baseline) to 13.97±2.82 (M:SD at 8th week), which is statistically significant with $p < 0.001$, effect size -1.59 and -26.24 % reduction in depressive symptoms (Figure 19 and Table 10).

Figure 19:

Depression scores within Group comparison.



Dep_Pre- Depression at Baseline; Dep_ Post- Depression after Intervention

Yoga group analysis showed a reduction in depressive scores from 18.28±2.44 (M:SD at baseline) to 9.05± 2.65 (M:SD at 8th week), which is statistically significant with $p < 0.001$, effect size -3.61 and -50.45% reduction in depressive symptoms (Figure 19 and Table 10).

Table-10:

Within group (pre and post) comparison

Parameters	Mean±SD (PRE)	Mean±SD (POST)	P (within groups)	Effect size (ES)	%Decrease
Control Group-DEP	18.94±3.38	13.97±2.82	<0.001*	1.59	26.24
Yoga Group-DEP	18.28±2.44	9.05±2.65	<0.001*	3.61	50.45

*p<0.05-significant; SD- Standard Deviation; %-Percentage; DEP-Depression scores

Similarly, Yoga group pre-post comparison of depression scores showed the mean ± Standard deviation at baseline was 18.28±2.44 and after eight weeks of Yoga intervention depression scores reduced to 9.05±2.65 which is statistically significant with the p value less than 0.001 and effect size of 3.61. There was a fifty percentage of decrease in the depression after the post intervention.

6.4.2 Between-group (Yoga vs. Control) Comparison

Independent t-test was used to analysed between (Yoga and Control) comparison, which showed insignificant difference in depressive scores at the baseline (18.94±3.38 and 18.28±2.44 with p=0.54) for both groups and a significant reduction in depressive scores (from 13.97±2.82 and 9.05±2.65) which statistically significant ($p < 0.001$; ES=1.796; 61.8 %). Analysis of the data revealed a statistically significant reduction in depression scores among participants in the Yoga group. These findings underscore the positive impact of Yoga on depression in pulmonary tuberculosis patients (Table 11).

Table-11:

Between groups (Yoga vs. Control) comparison

Depression Scores	Mean±SD	P (between groups)	ES	% Diff
Pre- DEP Control Group	18.94±3.38	<0.34** (NS)	1.796	61.8%
Pre- DEP Yoga Group	18.28±2.44			
Post- DEP Control Group	13.97±2.82	<0.001* (Sig diff)		
Post- DEP Yoga Group	9.05±2.65			

*p<0.05-Significant; **p>0.05- Not Significant (NS); Pre_ DEP - Depression at Baseline; Post_ DEP - Depression after Intervention; SD-Standard Deviation; ES-Effect Size

6.5 WHOQOL BREF-Quality of Life

6.5.1 Within Study (Yoga) group comparison

All the domains of QOL scores shows the significant improvement i.e., physical (*p is less than* 0.001), psychological (*p is less than* 0.001), and social (*p is less than* 0.001) except environmental domain is not significant with $p = 0.893$ by using paired t-test analysis as shown in Table-12.

Table-12: Within Yoga group comparison- Quality of Life Domains

QOL Domains	Yoga Group		Df	Effect Size	P
	Pre- Intervention (Mean ± SD)	**Post-** Intervention (Mean ± SD)			
Physical Domain QOL	35.98±4.24	79.05±7.54***	35	7.6037	<0.001
Psychological Domain QOL	47.04±7.48	69.90±11.22***	35	2.3898	<0.001
Social Domain QOL	35.99±2.66	48.26±4.15***	35	3.5173	<0.001
Environmental Domain QOL	49.30±9.52	51.38±12.15	35	0.1907	0.893(NS)

Data are expressed in Mean± Standard deviation; QOL- Quality of Life; SD-Standard Deviation; Statistical Test Used: Comparison of pre- and post intervention data was done using paired t-test. *P<0.05 was considered statistically significant, **P<0.01, ***P<0.001, NS-not significant, df-degree of freedom.

Physical Domain QOL:

The physical domain of the quality-of-life scores at the baseline was 35.98±4.24 (Mean ± Standard Deviation) and after eight weeks of Yoga intervention the QOL scores found to be 79.05±7.54 which is statistically significant with the p value less than 0.001, assuming P<0.05 was considered statistically significant and effect size of 7.603.

Psychological Domain QOL:

The Psychological domain of the quality-of-life scores at the baseline was 47.04±7.48 (Mean ± Standard Deviation) and after eight weeks of Yoga intervention the QOL scores found to be

69.90±11.22which is statistically significant with the p value less than 0.001, assuming P<0.05 was considered statistically significant and effect size of 2.3898.

Social Domain QOL:

The Social domain of the quality-of-life scores at the baseline was 35.99±2.66 (Mean ± Standard Deviation) and after eight weeks of Yoga intervention the QOL scores found to be 48.26±4.15 which is statistically significant with the p value less than 0.001, assuming P<0.05 was considered statistically significant and effect size of 3.5173.

Environmental Domain QOL:

The Environmental domain of the quality-of-life scores at the baseline was 49.30±9.52 (Mean ± Standard Deviation) and after eight weeks of Yoga intervention the QOL scores found to be 51.38±12.15 which is statistically insignificant with the p value less than 0.893, assuming P<0.05 was considered statistically significant and effect size of 0.1907.

6.5.2 Within Control group (post) comparison

The scores showed the improvement in physical ($p < 0.001$), psychological ($p < 0.001$), and social ($p < 0.001$) except environmental domain is not significant with $p = 0.88$ by using paired t-test analysis as shown in Table -13.

Table-13: Within Control group (pre and post) comparison- Quality of Life Domains

QOL Domains	Control Group		Df	Effect Size	P
	Pre- Intervention (Mean ± SD)	**Post-** Intervention (Mean ± SD)			
Physical Domain QOL	36.34±5.04	59.60±8.78***	35	3.248	<0.001
Psychological Domain QOL	48.09±13.00	58.91±11.95***	35	0.866	<0.001
Social Domain QOL	36.69±5.25	42.70±5.01***	35	1.171	<0.001
Environmental Domain QOL	48.26±13.15	51.38±12.15	35	0.006	0.882(NS)

Data are expressed in Mean± Standard deviation; QOL- Quality of Life; SD-Standard Deviation; Statistical Test Used: Comparison of date pre- and post intervention was done using paired t-test. *P<0.05 was considered statistically significant; ** P <0.01; *** P <0.001; NS-not significant. df-degree of freedom.

6.5.1.1 Physical Domain QOL:

The physical domain of the QOL scores at baseline was 36.34±5.04 (Mean ± Standard Deviation) and after eight weeks of standard intervention the QOL scores found to be 59.60±8.78which is statistically significant with the p value less than 0.001, assuming P<0.05 was considered statistically significant and effect size of 3.248.

6.5.1.2 Psychological Domain QOL:

The Psychological domain of the QOL scores in baseline was 48.09±13.00 (Mean ± Standard Deviation) and after eight weeks of standard of care intervention the QOL scores found to be 58.91±11.95 which is statistically significant with the p value less than 0.001, assuming P<0.05 was considered statistically significant and effect size of 0.866.

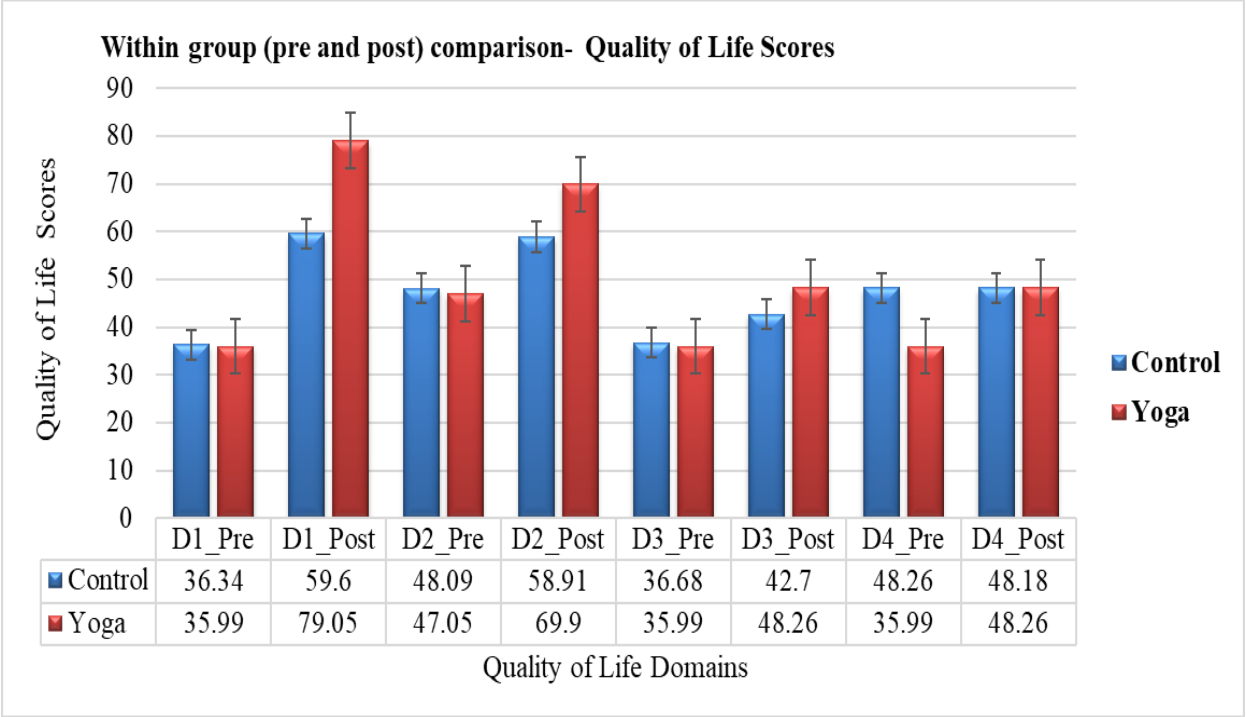
6.5.1.3 Social Domain QOL:

The Social domain of the QOL scores in the baseline was 36.69±5.25 (Mean ± Standard Deviation) and after eight weeks of standard of care intervention the QOL scores found to be 42.70±5.01which is statistically significant with the p value less than 0.001, assuming P<0.05 was considered statistically significant and effect size of 1.171.

6.5.1.4 Environmental Domain QOL:

Environmental domain of the QOL scores in baseline was 48.26±13.15 (Mean ± Standard Deviation) and after eight weeks of standard of care intervention the QOL scores found to be 51.38±12.15 which is statistically insignificant with the p value less than 0.882, assuming P<0.05 was considered statistically significant and effect size of 0.006 as shown in the Figure-20.

Figure-20: Within group (pre and post) Comparison of Quality-of-Life Scores:



	D1_Pre	D1_Post	D2_Pre	D2_Post	D3_Pre	D3_Post	D4_Pre	D4_Post
Control	36.34	59.6	48.09	58.91	36.68	42.7	48.26	48.18
Yoga	35.99	79.05	47.05	69.9	35.99	48.26	35.99	48.26

D1_Pre-Physical Domain scores at baseline, D1_Post- Physical Domain scores after 8 weeks; D2_Pre- Psychological Domain scores at baseline; D2_Pre- Psychological Domain scores after 8 weeks; D3_Pre-Social Domain scores at baseline; D3_Post-Social Domain scores after 8 weeks; D4_pre-environmental scores at baseline; D4_Post-Environmental scores after 8 weeks.

6.5.2 Between groups (Yoga vs. Control) comparison

Independent t-test was used to analysed between (Yoga and Control) comparison. At the baseline/ pre-intervention there was no difference between Yoga and control group as P>0.05. After the Yoga intervention there is an enhancement in quality-of-life scores with three domains of physical ($p < 0.001$), psychological ($p< 0.002$), and social (p< 0.001) except environmental domain (p=0.283) by using independent t-test analysis as shown in Table-14.

Table-14: Between groups (Yoga vs. Control) comparison

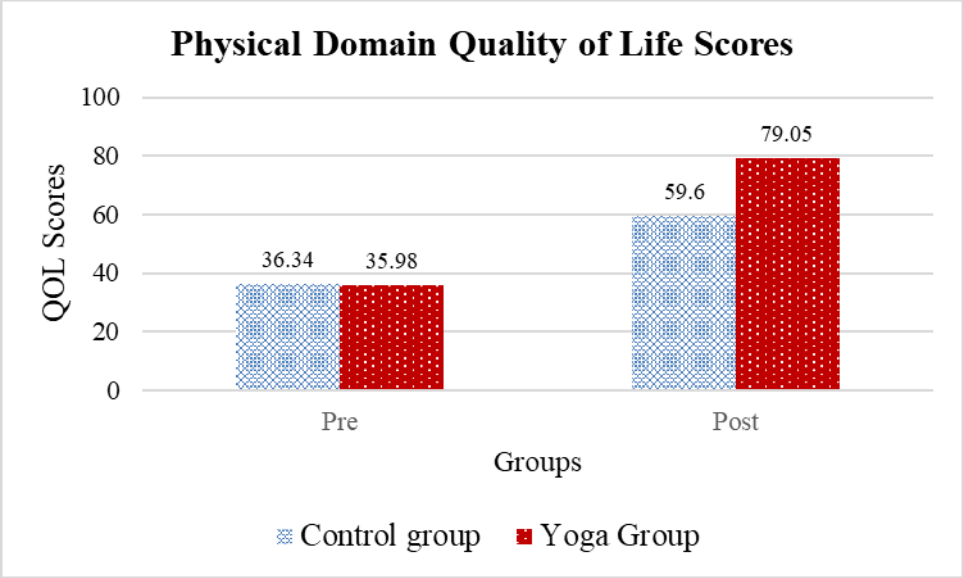
QOL Domains	Pre/Post Intervention	Between Groups		Df	P
		Control Group (Mean ± SD)	**Yoga Group** (Mean ± SD)		
Physical Domain QOL	Pre	36.34±5.04	35.98±4.24	70	0.633(NS)
	Post	59.60±8.78	79.05±7.54***	70	0.001
Psychological Domain QOL	Pre	48.09±13.00	47.04±7.48	70	0.699(NS)
	Post	58.91±11.95	69.90±11.22***	70	0.002
Social Domain QOL	Pre	36.69±5.25	35.99±2.66	70	0.653(NS)
	Post	42.70±5.01	48.26±4.15***	70	0.001
Environmental Domain QOL	Pre	48.26±13.15	49.30±9.52	70	0.656(NS)
	Post	48.30±11.68	51.38±12.15	70	0.283(NS)

Data are expressed in Mean± Standard deviation; QOL- Quality of Life; SD-Standard Deviation; Statistical Test Used: Between group Comparison (Control vs. Yoga) was done using independent t-test. * When P<0.05 was considered statistically significant; ** P <0.01; *** P <0.001; NS-not significant; df-degree of freedom.

6.5.2.1 Physical Domain QOL:

Between group (Yoga and Control) comparison, which showed insignificant difference in quality-of-life scores at the baseline (36.34±5.04 and 35.98±4.24 with p=0.633) for both groups and a significant improvement in quality-of-life scores after 8 weeks of intervention (from 59.60±8.78 and 79.05±7.54) which statistically significant ($p < 0.001$) as shown in Figure-21. Analysis of the data revealed a statistically significant improvement in QOL scores between the participants. These findings underscore the positive impact of Yoga on QOL in pulmonary tuberculosis patients.

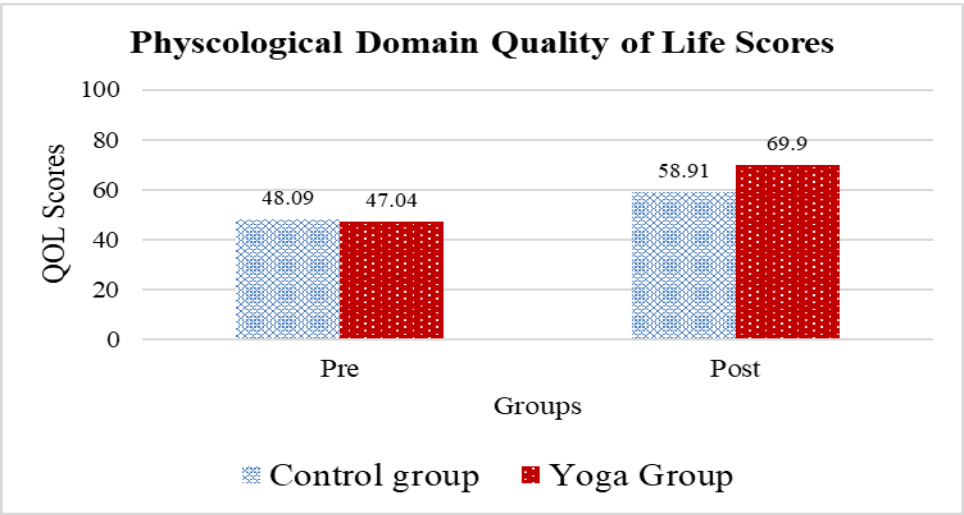
Figure-21: Between group (pre vs. post) Comparison of Physical Domain QOL Scores



6.5.2.2 Psychological Domain QOL:

Between group (Yoga and Control) comparison, which showed insignificant difference in quality-of-life scores at the baseline (48.09±13.00 and 47.04±7.48 with p=0.699) for both groups and a significantly improved as shown in Figure-20ent in quality-of-life scores after 8 weeks of intervention (from 58.91±11.95 and 69.90±11.22) which statistically significant ($p < 0.002$) as shown in Figure-22.

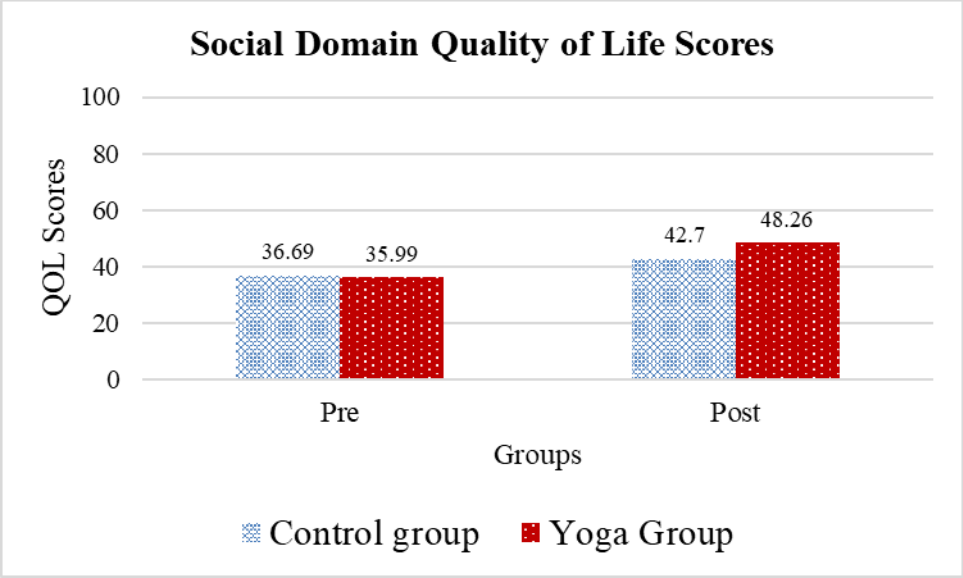
Figure-22: Between group (pre vs. post) Comparison of Psychological Domain QOL Scores



6.5.2.3 Social Domain QOL:

Between group (Yoga and Control) comparison, which showed insignificant difference in quality-of-life scores at the baseline (36.69±5.25 and 35.99±2.66 with p=0.653) for both groups and a significant improvement in quality-of-life scores after 8 weeks of intervention (from 42.70±5.01 and 48.26±4.15) which statistically significant ($p < 0.001$) as shown Figure 23.

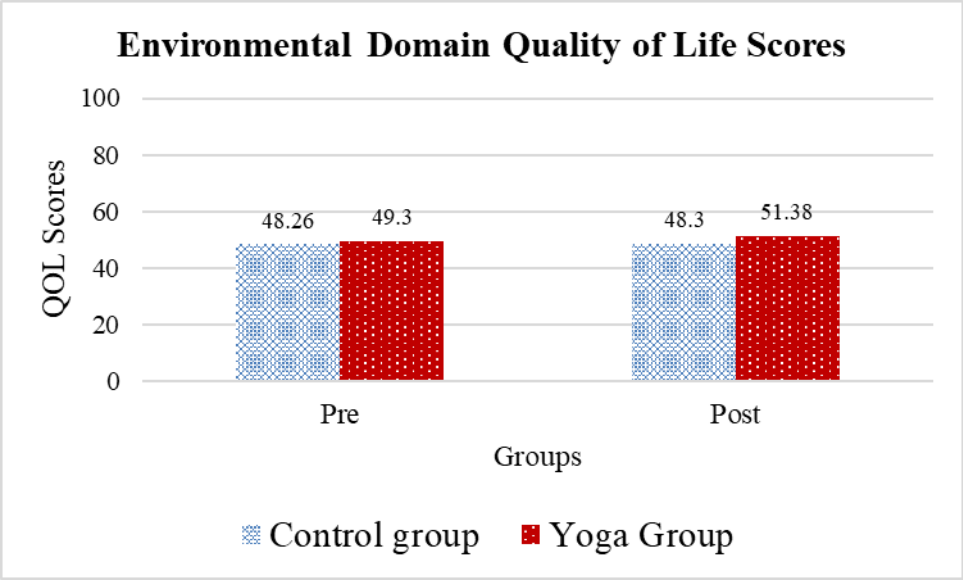
Figure-23: Between group (pre vs. post) Comparison of Social Domain QOL Scores



6.5.2.4 Environmental Domain QOL:

Between group (Yoga and Control) comparison, which showed insignificant difference in quality-of-life scores at the baseline (48.26±13.15 and 49.30±9.52 with p=0.653) for both groups and a no significant improvement in quality-of-life scores after 8 weeks of intervention (from 48.30±11.68 and 51.38±12.15) which statistically insignificant ($p < 0.283$) as showed in Figure-24.

Figure-24: Between group (pre vs. post) Comparison of Environmental Domain QOL Scores



There was a significant improvement in the quality-of -life scores in all the domains of Yoga group compared to the control group except in environmental domain after eight weeks of post intervention.

7 Chapter-7: Discussion

7.1 Objective I: Integrated Yoga and Pulmonary Function Test

Our results demonstrate a significant improvement in pulmonary function among patients who participated in the integrated Yoga intervention. The key PFT parameters, including forced vital capacity (FVC), forced expiratory volume in one second (FEV1), and ratio of % FEV1/FVC, showed notable enhancements in the Yoga group compared to the control group. Similar study results were found in the previous study by Naveen K V & Shirely telles (2004) which showed the improvement in infection, radiographic picture, weight gain and FVC after 60 minutes of Yoga for 2 months of practice. (41) The study conducted on Pulmonary Tuberculosis patients by A. Mooventhan et al. (2014), (110) and A K Singh et al. (2021) (82) showed significant improvement in pulmonary parameters after practicing Yoga.

In the similar way, research studies conducted on the asthma by Anshu et al. (2023), (111) E. Eva et al. (2018), (112) R. Vempati et al. (2009), (113) R. Das et al. (2022), (114) S Hiles et al. (2021), (115) Z Yang et al. (2016), (116) and M. Sangeetha Laxmi et al. (2023) (117) shows that Yoga module effectively improves pulmonary function parameters, along with the quality of life, levels of anxiety, and depression in people with bronchial asthma. On other hand, a study conducted by Gülyeter Erdoğan Yüce et al. (2020) (118) to evaluate the effects of pranayama on asthma control, PFT and quality of life concludes that pranayama improved the asthma control and asthma related QOL but doesn't show significant improvement in the pulmonary parameters.

In COPD patients who practiced Yoga had benefited and showed positive results from the research studies conducted by Yudhawati & Mariani Rasjid, 2019, (119) S. Artchoudane et al. (2018),(10) S. Sahasrabudhe et al. (2021), (120) D. Kaminsky et al. (2017), (121) and S. Malik et al. (2022) (122) were commented positively in improving the pulmonary parameters. In COVID-19 disease condition Yoga has positively impacted more on mental as well as physical aspects of breathing mechanism as studied by R. Dua et bal. (2023). (123)

The study by S. Snyder et al. (2021) (124) states that Yoga Interventions was carried out via video demonstration mode for Cancer Patients and their bystanders during the COVID-19 times has benefited and P. Jain Shrimal et al. (2023) and Srinivas M et al., studies suggests that integrated tele-Yoga might have therapeutic benefits in improving physiological, psychological, and mindfulness variables in asymptomatic COVID- 19 patients. (125,126) The study conducted by Ruchi Dua et al. (2024) on COPD patients 3 months pulmonary

rehabilitation includes 45 minutes of Yoga therapy and pulmonary rehabilitation had improved exercise capacity, HRQOL, symptoms sores, PFT and Depression and anxiety in patients.(123) The probable mechanisms responsible for the observed improvements in PFT parameters could be multifactorial. Yoga involves a combination of physical postures, breathing exercises, and meditation techniques. The deep breathing exercises, specifically pranayama, may have contributed to enhanced respiratory muscle strength and improved lung capacity study conducted by Jerath et al., 2006. (127) Additionally study by Santana et al., 2013, the relaxation techniques incorporated in Yoga may have positively influenced the overall well-being of the participants, indirectly impacting their respiratory function. (128)

The integration of Yoga into the conventional management of pulmonary TB holds promise as a complementary therapeutic approach.(94) Yoga's holistic nature, addressing both physical and mental aspects, aligns with the comprehensive care required for TB patients. Beyond the evident physiological improvements, the psychological benefits of Yoga, such as stress reduction and improved mental health, may further contribute to the overall well-being of individuals undergoing TB treatment.

One notable aspect of this study was the high adherence rate observed in the Yoga group. The participants reported a positive experience with the Yoga sessions, suggesting that integrating Yoga into the standard care regimen for TB patients is not only feasible but also well-received. The accessibility and simplicity of the Yoga interventions make them a potentially sustainable and cost-effective adjunctive therapy for TB management.

7.1.1 Implications for Public Health:

The findings of this RCT have broader implications for public health, particularly in the Asia and Africa regions with a high prevalence of TB. Integrating Yoga into the treatment protocol for pulmonary TB could potentially lead to improved treatment outcomes, reduced complications, and a better quality of life for affected individuals. Future research should explore the long-term effects of integrated Yoga on TB outcomes and assess its scalability in diverse healthcare settings.

7.2 Objective II: Integrated Yoga and Depression

The present study intended to evaluate the effect of integrated Yoga as an adjuvant to standard care on depressive symptoms in patients with PTB. We observed a significant reduction in depressive symptoms after eight weeks of intervention, suggesting that integrated Yoga positively impacts the management of PTB. Integrated Yoga was administered both Offline and Online mode. All participants were able to perform both methods of Yoga practice. No adverse effects were reported during the entire intervention period with nil attrition. It shows that integrated Yoga is feasible and leads to excellent compliance.

Literature showed only one study was carried out by Naveen KV et. al., which focused only on parameters related to pulmonary function in patients with PTB. (41) To the best of our knowledge, this is the first RCT addressing the depressive symptoms in patients with PTB.

However, we have observed many studies that show that different forms and components of Yoga reduced depression in respiratory as well as in other disease conditions.(129,130) The Yoga therapy studies by Sangeethalaxmi & Hankey, 2022 and Santino et al., 2020 on bronchial asthma patients showed significantly improved depression, anxiety, pulmonary functions, and quality of life in the patients. (117,131)

Studies on the effect of Yoga on chronic obstructive pulmonary disease (COPD) by Ranjita et al., 2016 have shown the positive impact of Yoga on the assessment of health status, depression, and anxiety in coal miners. (132) The study by Barassi et al., 2018 on Yoga breathing exercises on Lung cancer patients effectively alleviated perioperative symptoms of lung resection patients. (133)

Several mechanisms could contribute to the observed reduction in depression among the Yoga group participants. Firstly, the physical aspect of Yoga can stimulate release of endorphins, the body's natural "feel-good" hormones, which can alleviate symptoms of depression. Secondly, Yoga promotes relaxation and stress reduction, which can counteract the heightened stress levels commonly experienced by patients with PTB. Pranayama and its effects are well established. (134) Likewise the research by Nuzhath FJ et al. 2024, Pranayama and Yoga Nidra has effect on other diseases such as cervical cancer patients that improved the anxiety and depression after six weeks of practice. (135)

The experience of dealing with a chronic illness like PTB can be emotionally distressing, and patients may face symptoms of anxiety and depression. These symptoms can further impact PTB patients' overall health-related quality of life as per the research work by Sartika et al., 2019; Sweetland et al., 2019. (28,136) Yoga has been reported to be beneficial in reducing

anxiety and depression symptoms in various populations. (88) Incorporating Yoga into the treatment regimen of TB patients as per Jasti et al., 2020 may aid in alleviating mood-related challenges and enhancing emotional well-being. (137) Sleep disturbances are common in patients with TB and can worsen anxiety and depression. (74) Pranayama is one of the essential components of Yoga therapy, which is slow and rhythmical breathing, which helps to correct breathing and enhances the "vital breath" and cardiovascular and respiratory functions. It is also found beneficial in balancing the mind by increasing parasympathetic and decreasing sympathetic activity. Thus, reducing anxiety and other emotional components. (138) Studies showed that pranayama may modulate the activity brain areas involved in emotional processing, specifically the amygdala, anterior cingulate, anterior insula, and prefrontal cortex. (139) Moreover, Yoga Nidra (mindfulness) meditation, a central component of Yoga, encourages participants to focus on the present moment, reducing rumination and promoting emotional stability. So, Yoga has a positive effect on alleviating the depression effect in different disease conditions, with minor to significant changes in the depressive scores, similar results were observed in the present study.

7.2.1 Implications of the study:

The findings of this randomized controlled trial provide valuable insights into the potential of Yoga as an adjunctive therapy for patients with pulmonary tuberculosis experiencing depression. Integrating Yoga into the NTEP treatment regimen could offer a holistic approach to addressing the mental health challenges associated with the disease. This study bridges the gap between traditional medical practices and holistic approaches, demonstrating complementary therapies' potential to improve mental health outcomes.

7.3 Objective III: Integrated Yoga and WHO-BREF Quality of Life:

The Yoga group also experienced a significant enhancement in their quality of life, as assessed through the WHO BREF-QOL questionnaire. The study implies that this improvement in quality of life might be attributed to the stress-relieving effects of Yoga and its potential to enhance respiratory function. The subdomains of QOL of life mainly physical domain, psychological and social domains scores improved and showed significant effect compared to control group. Whereas environmental domain scores were insignificant compared to standard of care.

Similar outcomes were observed in a prior randomized controlled trial, which demonstrated enhancements in quality of life, pulmonary function, reduced symptom severity, and increased rates of sputum conversion. Additionally, another case report documented improvements in health-related quality of life, symptom severity, weight gain, and pulmonary parameters following eight weeks of Yoga practice as shown in the study conducted by Mooventhan et al., 2014.(110)

Similar findings have been noted in studies by Erdoğan Yüce & Taşcı, 2020; Sangeethalaxmi & Hankey, 2022; Yadav et al., 2021 focusing on other respiratory conditions, such as asthma, where interventions like Yoga have demonstrated improvements in quality of life. (117,118,140) In the same way positive improvement has been observed in Chronic Obstructive Pulmonary Disorder condition as mentioned in the research studies conducted by Artchoudane et al., 2018; Yudhawati & Mariani Rasjid, 2019; Zhang et al., 2022. (10,119,141) In the similar respiratory disease conditions like Lung cancer,(Milbury et al., 2015) and COVID-19 (Kandula & Wake, 2021; Sayin Kasar & Karaman, 2021) found improvement in quality of life.(142–144) In Indonesia, a study examined the impact of Yoga on breathlessness symptoms in 34 patients with pulmonary tuberculosis (PTB), revealing that those who practiced Yoga experienced an improvement in breathlessness symptoms. Consequently, the study suggests that Yoga could serve as a beneficial respiratory management intervention for PTB patients (Dadang et al., 2021).(145) Similarly, another study conducted in Himachal Pradesh, India, focused on tuberculosis patients who engaged in yogic exercises. It found that these patients showed enhancements in various pulmonary parameters such as forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), FEV1/FVC ratio, and peak expiratory flow rate (PEFR), leading to a reduction in respiratory distress. (82)

Yoga has improved the quality of life in other disease conditions such as low back pain in nurses as conducted by Patil NJ et al., (2018) that Yoga has demonstrated greater enhancements in the physical, psychological, and social aspects of quality of life compared to physical exercises among nursing professionals with chronic low back pain. (146)

Yoga has been shown to improve autonomic functions by activating neuro-hormonal mechanisms, which suppress sympathetic activity by downregulating the hypothalamic-pituitary-adrenal axis. (134) Furthermore, research suggests that manipulated nostril breathing could potentially affect systolic and diastolic pressure, indicating a therapeutic effect of Yoga. (147)

In terms of quality of life, the physical domain of the WHOQOL-BREF encompasses aspects like sleep, mobility, fatigue, pain, and work capacity. Findings from the study indicate that the experimental group experienced greater improvement in these domains compared to the control group, potentially due to Yoga's impact on reducing pain, fatigue, sleep disturbances, and enhancing mobility.(148)

Regarding the psychological domain, improvements in the Yoga group were observed across various facets such as learning, emotions, spirituality, cognition, self-esteem, and memory, compared to the control group. This enhancement could be attributed to reduced levels of stress, anxiety, and depression among participants. (136)

Additionally, the social domain scores were higher in the Yoga intervention group, indicating improved interpersonal relationships and social support among pulmonary tuberculosis patients. However, no significant changes were noted in the environmental domain, possibly due to the consistent home environment throughout the study period.(148)

The randomized controlled trial design of the study underscores several strengths, including Yoga's ability to address psychological issues effectively, its non-invasive nature, cost-effectiveness, and ease of learning and practice. Notably, this study marks the first interventional investigation of Yoga's impact on health-related aspects of quality of life in pulmonary tuberculosis patients. However, it's important to acknowledge certain limitations, such as the small sample size, limited geographical coverage, and lack of assessment during the continuation phase of tuberculosis treatment. Further research with larger sample sizes is warranted to validate these findings. Overall, the study provides valuable evidence supporting the use of Yoga as a complementary therapy for the National Tuberculosis Elimination Program (NTEP) to enhance the quality of life among patients with pulmonary tuberculosis.

7.3.1 Limitation of the study:

Only a few randomized controlled trials have explored the impact of Yoga on the quality of life of patients with pulmonary tuberculosis. Monitoring patients regularly at home poses potential challenges and may introduce observer bias.

However, it's important to acknowledge several limitations. These include a small sample size, limited geographic coverage (only one district), lack of assessment during the continuation phase of TB treatment, and the need for further research to validate these results.

7.3.2 Recommendations to the public and public policy:

Considering the manifold benefits that Yoga offers, especially in alleviating the physical and mental burden on Pulmonary Tuberculosis (PTB) patients, we strongly recommend the integration of Yoga into the National Tuberculosis Elimination Programme (NTEP). Yoga's holistic approach, encompassing physical postures, controlled breathing, meditation, and relaxation techniques, can significantly enhance the well-being of PTB patients.

This recommendation underscores the importance of developing and implementing clear policies within the NTEP framework. These policies should prioritize patient education, ensuring that PTB patients are aware of Yoga's potential benefits as an adjunct therapy. Furthermore, research initiatives should be supported to gauge the long-term impact of Yoga on PTB patients' mental and physical health, facilitating evidence-based decision-making.

By embracing Yoga as a complementary therapy, we empower PTB patients to take an active role in their healing journey, fostering a more comprehensive and patient-centered approach within the NTEP. This inclusive policy shift holds the potential to significantly improve the quality of life for PTB patients, addressing not only the physical but also the psychological aspects of their condition.

Chapter-8: Summary

The study examined the potential benefits of integrating Yoga as an adjuvant therapy alongside standard care for patients with pulmonary tuberculosis (PTB). It found that integrated Yoga positively influenced pulmonary function and led to a reduction in depressive symptoms and enhances the health-related quality of life among PTB patients. These findings suggest that Yoga could enhance both physical and mental well-being in PTB patients, potentially improving treatment outcomes and overall quality of life. However, the study highlighted the need for larger, multicentric trials with longer follow-up periods to validate these findings and explore Yoga's impact on other aspects of TB management, such as medication adherence and immune response. Overall, the study underscores the potential of Yoga as an adjuvant treatment in PTB management and calls for further research to fully establish its role in improving outcomes for individuals affected by the disease.

9. APPRAISAL & SWOC ANALYSIS

9.1 Objective 1:

To Evaluate the Effect of integrated Yoga as an adjuvant therapy to National Tuberculosis Elimination Programme (NTEP) on Pulmonary Functions in patients with Pulmonary Tuberculosis.

Conclusion:

The present study suggests that integrated Yoga may be an adjuvant therapy to standard care that positively influences pulmonary functions in patients with pulmonary tuberculosis. The results pave the way for further exploration of Yoga as a complementary therapy in TB management and underscore the need for larger, more extended studies to establish its role in improving overall outcomes for individuals affected by this infectious disease.

9.1.1 Implications for Public Health:

The findings of this Randomized Controlled Trial (RCT) have broader implications for public health, particularly in the Asia and Africa regions with a high prevalence of TB. Integrating Yoga into the treatment protocol for pulmonary TB could potentially lead to improved Pulmonary function parameters that in turn helps the treatment outcomes, reduced complications, a better adherence, and overall wellbeing for affected individuals. Future research should explore the long-term effects of integrated Yoga on TB outcomes and assess its scalability in diverse healthcare settings.

9.1.2 Weaknesses and Opportunities:

While our study provides valuable insights, certain limitations must be acknowledged. The sample size was relatively small, and the study duration was limited. Future research with multicentric and longer follow-up periods is warranted to validate our findings. Additionally, exploring the impact of Yoga on other aspects of TB management, such as medication adherence and immune response, could provide a more comprehensive understanding of its potential benefits.

9.2 Objective 2:

To evaluate the effect of integrated Yoga as an adjuvant therapy to National Tuberculosis Elimination Programme (NTEP) on assessing the Depression in patients with Pulmonary Tuberculosis.

Conclusion:

The present study confirmed a higher reduction in depressive symptoms in the Yoga group (adjuvant to NTEP) compared to the Control group (NTEP) in patients with pulmonary tuberculosis. Yoga therapy may be incorporated into NTEP as a complementary therapy to enhance psychological well-being in patients with PTB. Multi-centric, robust designs with long-term interventions are warranted.

9.2.1 Implications of the study:

The findings of this randomized controlled trial provide valuable insights into the potential of Yoga as an adjunctive therapy for patients with pulmonary tuberculosis to reduce the depression. Integrating Yoga into the NTEP treatment regimen could offer a holistic approach to addressing the mental health challenges associated with the disease. This study bridges the gap between traditional medical practices and holistic approaches, demonstrating complementary therapies' potential to improve mental health outcomes.

9.2.2 Strengths and Weaknesses of the study:

This was the first RCT to evaluate the effect of Integrated Yoga on depressive symptoms in patients with PTB with excellent compliance through the intervention. However, this single-center study was restricted to one district; future multi-centered trials with large sample sizes and long-term interventions are warranted.

9.3 Objective 3:

To evaluate the effect of integrated Yoga as an adjuvant therapy to National Tuberculosis Elimination Programme (NTEP) on assessing the health-related Quality of Life in patients with Pulmonary Tuberculosis.

Conclusion:

The research evidence endorses the use of Yoga as an adjuvant treatment for patients undergoing the National Tuberculosis Elimination Program (NTEP) in patients with pulmonary tuberculosis (PTB) to enhance their health-related quality of life. By improving both Quality of Life and respiratory function, Yoga may assist patients in effectively managing the physical and psychological burdens associated with TB, potentially resulting in improved treatment outcomes and overall Quality of Life.

9.3.1 Implications for Public Health:

The findings of this Randomized Controlled Trial have broader implications for public health, particularly in the countries with a high prevalence of TB. Integrating Yoga into the treatment protocol for pulmonary TB could potentially lead to improved treatment outcomes, reduced complications, and a better quality of life for affected individuals. Future research should explore the long-term effects of integrated Yoga on TB outcomes and assess its implementation in diverse healthcare settings.

9.3.2 Strengths and Weakness:

The randomized controlled trial (RCT) design of the study provided several strengths, particularly in demonstrating Yoga's effectiveness in addressing psychological issues. Additionally, Yoga was found to be non-invasive, cost-effective, and easy to learn and practice. Notably, this study marked the first interventional investigation of Yoga's impact on health-related aspects of quality of life in pulmonary tuberculosis (PTB). However, it's crucial to acknowledge certain limitations, including the small sample size, coverage limited to a single district, and the lack of assessment during the continuation phase of TB treatment. Further research is warranted to validate these findings.

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APPENDIX I-A

Publications from Ph.D. Work

Articles-02:

1. Srinivas, M.; Patil, N. J.; Prabhakar, K.; Jagmohan, S. V. Effect of Yoga on Quality of Life in Patients with Pulmonary Tuberculosis: A Randomized Control Trial. International Journal of Yoga 16(3):p 185-191, Sep–Dec 2023. | DOI: 10.4103/ijoy.ijoy_208_23 **(PubMed, Web of science, UGC Care and IF-1.6)**

2. Srinivas M., Patil N.J., Jagmohan S.V., Prabhakar K., Dhanashri Patil and Guruprasad T.J.: Yoga and quality of life in pulmonary tuberculosis patients during COVID-19 and post- COVID-19: A narrative review. Intern. J. Zool. Invest. 9(Special Issue 2): 252-260, 2023. https://doi.org/10.33745/ijzi.2023.v09ispl2.044 **(Web of science)**

Presentations-02

SI.NO	Presentation Title	International/ National Conference type	Date/Venue	Remarks
01	A Randomized Control Trial to Evaluate the effect of Integrated Yoga on Depression in Patients with Pulmonary Tuberculosis	International Conference- **YANTRA-2023**	24th&25th November 2023 organized by **National Institute of Mental Health and Neurosciences -NIMHANS**	Received a **Best Paper Award** (3rd Prize)
02	Effect of Integrated Yoga on patients with Pulmonary Tuberculosis: A Randomized Controlled Trial	National Conference- **Pulmonary Rehabilitation-2023**	22nd December 2023 organized by **Sri Devaraj Urs Medical College**	**Best Scientific Presentation Award** (1st Prize)

Article-01

Original Article

Effect of Yoga on Quality of Life in Patients with Pulmonary Tuberculosis: A Randomized Control Trial

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Abstract

Introduction: Yoga is emerging as one of the holistic approaches to respiratory diseases. The scope of yoga is expanding in communicable diseases with physical, mental, and societal benefits. **Aim and Objective:** The present study aims to evaluate the effect of integrated yoga as an adjuvant therapy to the National Tuberculosis Elimination Programme (NTEP) on assessing health-related Quality of Life (QoL) in patients with pulmonary tuberculosis (PTB). **Setting and Design:** A randomized controlled trail study was conducted in a tertiary care teaching hospital. **Methodology:** The study screened 826 PTB patients; 72 patients were found suitable and agreed to participate. The PTB patients were randomly assigned to either a yoga group (n = 36) or a control group (n = 36) using the sequentially numbered opaque sealed envelope technique. The control group received standard-of-care treatment as per NTEP, and the yoga group practiced 45 min of integrated yoga for 8 weeks along with standard of care. The World Health Organization Quality of Life (WHOQOL-BREF) questionnaire was used to collect the data at baseline and after 8 weeks of intervention. **Results:** The results of within-group comparisons in both the groups showed that there was a significant improvement in physical ($P < 0.01$), psychological ($P < 0.01$), and social ($P < 0.01$), with $P \leq 0.05$ being considered statistically significant except environmental domain. Between groups, analysis shows that in the preintervention, there was no difference between the yoga and control group as $P > 0.05$. After the yoga intervention, there was an enhancement in QoL scores with three domains except the environmental domain ($P = 0.28$). **Conclusion:** The study evidence supports the use of yoga as a complementary therapy for the NTEP in patients with PTB may improve their QoL.

Keywords: *Integrated yoga, pulmonary tuberculosis, quality of life, yoga, yoga therapy*

Introduction

Pulmonary tuberculosis (PTB) is a contagious bacterial infection that primarily affects the lungs and can cause significant morbidity and mortality. The World Health Organization (WHO) report 2022 shows that 10.6 million incidence cases among 1.4 million deaths occurred in 2021.[1-3] India is one of the major contributors to TB.[4] While there have been significant improvements in tuberculosis (TB) treatment over the past few decades, the disease remains a significant global health problem, particularly in low-income and middle-income countries. In many parts of the world, TB patients continue to experience significant social, economic, and psychological challenges that can impact their quality of life (QoL) and can lead to symptoms such as coughing, fever, weight loss, night sweats, anxiety and depression, and fatigue.[5-7] All of these can significantly impact their daily lives and lead to lower QoL in TB patients. In addition, the side effects of TB medications, such as nausea, vomiting, and liver damage, can further impact a patient's QoL. The standard treatment for TB typically involves a combination of antibiotics for patients' recovery, but complementary therapies such as yoga may also support patients' health and well-being. Yoga is a form of mind-body practice that combines physical postures, breathing techniques, and meditation or relaxation exercises. Previous research has suggested that yoga may have a range of health benefits for other respiratory disorders like asthma, chronic obstructive pulmonary disease, lung cancer, and COVID-19, such as reducing stress and anxiety, improving mood, improving physical function, and enhancing

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the QoL.[8-12] In the current scenario, very few randomized studies are available on Yoga and PTB. Hence, the present study suggests the complementary role of yoga therapy in PTB patients to enhance their health-related QoL.

Methodology

The study was conducted at the department of pulmonology, a tertiary care teaching hospital. The Institutional Ethical Committee of Sri Devaraj Urs Academy of Higher Education and Research has approved the study (SDUAHER/IEC/MJ/13/22-23), and the study was registered under the CTRI (CTRI/2023/01/049012). The study was conducted from January 2023 to September 2023. It was a randomized control trial design. The sample size was calculated using nMaster 2.0 software. which was developed by the Biostatistics Training and Resource Center, Department of Biostatistics, Christian Medical College, Vellore, Tamil Nadu, India. Based on the forced expiratory volume in 1 second (FEV_1), as reported in the study conducted by Visweswaraiah and Telles (2004) reported that an average variance estimated of 0.16 in FEV_1.[7] Considering the power of 90% with Alpha error of 0.05. The sample estimated per group was 30. The final estimated sample size per group was 36, and the overall sample size was 72, with a dropout rate of 20%. The study participants were selected based on the inclusion criteria: new cases of microbiologically diagnosed and clinically diagnosed PTB patients who will be receiving treatment under the National Tuberculosis Elimination Programme (NTEP); age group of patients between 18 and 60 years; and both male and female patients with PTB. The exclusion criteria are as follows: TB with HIV; multiple drug resistance MDR-TB; PTB with HIV; Extra PTB; patients with psychosis and delirium; no recent major surgeries in the last 4 months; and any form of yoga practice in the last 3 months excluded from the study. Before commencement of the study, the purpose and complete procedures were clearly explained to the participants and their caretakers. Then, written informed consent was obtained voluntarily from each participant.

Randomization procedure

The study screened 826 PTB patients; 754 patients were excluded due to not meeting the inclusion criteria, and 72 patients were found suitable and agreed to participate. The PTB patients were randomly assigned to either a yoga group or a control group using the sequentially numbered opaque sealed envelope technique. Each envelope is of the same size and written as Group A (control) and Group B (experiential/yoga) separately mentioned in each envelope. The Group's A and B envelopes were mixed after writing inside the envelope. When the patients visited the department of pulmonology, they were asked to pick up an opaque sealed envelope. Thirty-six participants got Group-A envelopes; the other 36 got Group-B. Finally, 72 patients completed the study, as shown in Figure 1. The experimental group participants received 45-min yoga session 5 days a week for 8 weeks, while the control group received standard care, i.e., anti-TB drugs as per weight band in NTEP.

Control group intervention

The control group intervened with standard-of-care treatment. Newly diagnosed PTB patients received the first line of anti-TB drugs, i.e., (isoniazid [H], rifampicin [R], pyrazinamide [Z], and ethambutol [E] [HRZE]) during the intensive phase of treatment as per the NTEP for 8 weeks. This four HRZE drugs were administered as per weight band-based fixed-dosage combination.[13]

Fixed-dose combination provides a simple approach to deliver the correct number of drugs at the right dosage as all the necessary drugs are combined in a single tablet. It is used to deliver H/R/Z/E drugs of anti-TB treatment.[14]

Yoga intervention

Yoga intervention consists of breathing exercises, loosening exercises, asanas (postures), pranayama (breathing exercises), relaxation techniques and meditation, and standard-of-care treatment. Initially, five sessions will be taught to the patients by a yoga trainer, and later, we have made an exclusive 45-min video of the yoga module with clear instructions to follow regularly, as shown in Table 1. The patient's adherence to daily yoga practice at their homes was checked and enquired through telephone calls and visits to their home once every 2 weeks. We informed all patients that any difficulty in practice or adverse effects needs to be brought to the notice of the investigator.

Table 1: Integrated yoga module

Name of the practice	Duration (min)
Breathing exercises	6
Hands in and out breathing	
Hands stretch breathing	
Sasankasana breathing (moon pose)	
Loosening exercises	4
Shoulder rotation	
Forward and backward bending ×3 rounds	
Instant relaxation technique	
Yogasanas/physical postures	10
Ardhakati cakrasana (lateral arc pose)	
Ardha cakrasana (half wheel pose)	
Bhujangasana (serpent pose)	
Deep relaxation technique	
Pranayama	15
Vibhagya pranayama (sectional breathing)	
Nadisudhi pranayama (alternate nostril breathing)	
Bhramari pranayama (bee breathing)	
Nadanusandhan	
Relaxation	10
Yoga nidra (guided meditation)	
Total duration	45

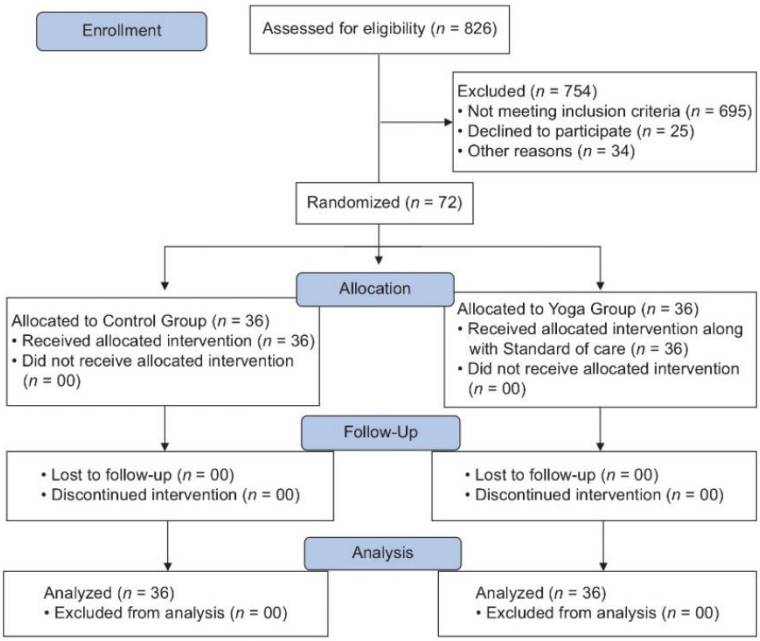

Figure 1: CONSORT flow diagram

Outcome measure

The WHOQoL-BREF, Health-related QoL questionnaire was administered by someone not involved in the study. In total, 10% of participants questionnaires were verified by someone not a part of the research team and designated not less than the assistant professor to nullify confounding investigators' bias variable. The baseline data were collected before the start of the intervention and after the intervention in the 8th week. The WHOQoL-BREF questionnaire comprises 26 items that provide information regarding four broad domains: physical health, psychological health, social relationships, and environment.[15]

Statistical analysis

Data analysis was carried out using SPSS software Windows Version 23.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp). Normality was checked using Shapiro–Wilk test and the data were found normally distributed. We expressed data in terms of mean ± standard deviation and effect of intervention was analyzed using paired *t*-test for within group analysis. The between group analysis was done using independent *t*-test. $P < 0.05$ was considered statistically significant.

Results

The 72 participants were in the mean age of 45 ± 10.04 in males and 45.95 ± 10.63 in females. Among the participants, 60 (83.3%) were married and 12 (16.7%) were unmarried. In India incidence of PTB patients is lower in female compared to male.[16] Other socioeconomic factors like gender, education, habitat, and marital status are shown in Table 2.

Within study (yoga) group comparison of World Health Organization Quality of Life-BREF scores

All the domains of QoL scores showed that the significant improvement, i.e., physical ($P < 0.001$), psychological ($P < 0.001$), and social ($P < 0.001$) except environmental domain, was not significant with $P = 0.893$ using paired *t*-test analysis as shown in Table 3.

Within control group (pre and post) comparison of World Health Organization Quality of Life-BREF scores

The scores showed that the improvement in physical ($P < 0.001$), psychological ($P < 0.001$), and social ($P < 0.001$) except environmental domain was not significant with $P = 0.88$ using paired *t*-test analysis as shown in Table 4.

Between groups (yoga vs. control) comparison of World Health Organization Quality of Life-BREF

At the baseline/preintervention, there was no difference between yoga and control group as $P > 0.05$. After the yoga intervention, there was an enhancement in QoL scores with three domains of physical ($P < 0.001$),

Table 2: Socioeconomic data

Characteristics	All participants	Control group, *n* (%)	Yoga group, *n* (%)
Gender	Male - 52 (72.22)	24 (67)	28 (78)
	Female - 20 (27.77)	12 (33)	8 (22)
Age (mean±SD)	Male - 45±10.04	46.54±10.75	45.21±9.74
	Female - 45.95±10.63	46.83±9.47	44.62±13.35
Marital status	Married - 60 (83.3)	32 (89)	28 (78)
	Unmarried - 12 (16.7)	4 (11)	8 (22)
Education	Uneducated - 20 (27.8)	13 (36)	7 (19)
	Primary school - 12 (16.7)	7 (19)	5 (14)
	Middle school - 12 (16.7)	8 (22)	4 (11)
	High school - 16 (22.2)	7 (19)	9 (25)
	Preuniversity - 6 (8.3)	0	6 (17)
	Graduation and above - 6 (8.3)	1 (3)	5 (14)
Habitat	Rural - 46 (63.9)	22 (61)	24 (67)
	Urban - 8 (11.1)	4 (11)	4 (11)

n: Number of participants, SD: Standard deviation

Table 3: Within yoga group comparison - quality of life domains

QoL domains	Yoga group (mean±SD)		Df	Effect size	*P*
	Preintervention	Postintervention			
Physical domain QoL	35.98±4.24	79.05±7.54*	35	7.6037	<0.001
Psychological domain QoL	47.04±7.48	69.90±11.22*	35	2.3898	<0.001
Social domain QoL	35.99±2.66	48.26±4.15*	35	3.5173	<0.001
Environmental domain QoL	49.30±9.52	51.38±12.15	35	0.1907	0.893 (NS)

Data are expressed in Mean± Standard deviation, QOL- Quality of Life, SD-Standard Deviation, Statistical Test Used: Comparison of pre- and post intervention data was done using paired *t*-test. $P<0.05$ was considered statistically significant; *$P<0.001$- highly significant, NS-Not significant, Df-Degree of freedom

Table 4: Within control group pre- and post-comparison - quality of life domains

QOL domains	Control group, mean±SD		Df	Effect size	*P*
	Preintervention	Postintervention			
Physical domain QoL	36.34±5.04	59.60±8.78*	35	3.248	<0.001
Psychological domain QoL	48.09±13.00	58.91±11.95*	35	0.866	<0.001
Social domain QoL	36.69±5.25	42.70±5.01*	35	1.171	<0.001
Environmental domain QoL	48.26±13.15	51.38±12.15	35	0.006	0.882 (NS)

Data are expressed in Mean± Standard deviation, QOL- Quality of Life, SD-Standard Deviation, Statistical Test Used: Comparison of date pre- and post intervention was done using paired *t*-test. $P<0.05$ was considered statistically significant; *$P<0.001$- highly significant, NS-Not significant, Df-Degree of freedom

psychological ($P < 0.002$), and social ($P < 0.001$) except environmental domain ($P = 0.283$) using independent *t*-test analysis as shown in Table 5.

There was a significant improvement in the yoga group compared to the control group after 8 weeks of postintervention.

Discussion

The yoga group also significantly improved their QoL, as measured by the WHO BREF-QoL questionnaire. The study suggests that the improvement in QoL may be due to the stress-reducing effects of yoga and its potential to improve respiratory function.

Similar results were obtained in the previous randomized control trial showing improvement in QoL, pulmonary function, reduced symptoms scores, and sputum conversion rates. One more case report suggests that after 8 weeks of yoga, there is an improvement in health-related QoL, symptoms scores, weight gain, and pulmonary parameters.[6]

Similar study results were found in other respiratory diseases by improving the QoL in asthma,[7-19] chronic obstructive pulmonary disorder,[20-22] lung cancer,[11] and COVID-19.[23,24] The effects of yoga on symptoms of breathlessness in 34 patients with PTB were assessed in Indonesia and observed that who practices yoga there was an improvement in breathlessness symptoms. Hence, the study adds that yoga can be a respiratory management intervention in PTB.[25] Another study on Tuberculosis patients in Himachal Pradesh, India, who practice yogic exercises found that they improved their pulmonary

Table 5: Between groups (yoga vs. control) comparison

QoL domains	Pre/post-intervention	Between groups (mean±SD)		Df	*P*
		Control group	Yoga group		
Physical domain QoL	Pre	36.34±5.04	35.98±4.24	70	0.633 (NS)
	Post	59.60±8.78	79.05±7.54*	70	0.001
Psychological domain QoL	Pre	48.09±13.00	47.04±7.48	70	0.699 (NS)
	Post	58.91±11.95	69.90±11.22*	70	0.002
Social domain QoL	Pre	36.69±5.25	35.99±2.66	70	0.653 (NS)
	Post	42.70±5.01	48.26±4.15*	70	0.001
Environmental domain QoL	Pre	48.26±13.15	49.30±9.52	70	0.656 (NS)
	Post	48.30±11.68	51.38±12.15	70	0.283 (NS)

Data are expressed in Mean± Standard deviation, QOL- Quality of Life, SD-Standard Deviation, Statistical Test Used: Between group Comparison (Control vs. Yoga) was done using independent *t*-test. When $P<0.05$ was considered statistically significant, *$P<0.001$-highly significant, NS-not significant, Df-Degree of freedom

parameters, i.e., forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), FEV1/FVC ratio, and peak expiratory flow rate (PEFR), thereby reducing respiratory distress.[26]

The underline mechanism that yoga acts to improve autonomic functions by triggering neurohormonal mechanisms by the suppression of sympathetic activity through downregulation of the hypothalamic–pituitary–adrenal axis.[27] The study suggests that manipulated nostril breathing could alter the systolic and diastolic pressure shows the possible therapeutic effect of yoga.[28]

The physical domain of WHOQOL-BREF includes sleep, mobility, fatigue, pain, and work capacity. Study results suggest that improvement in the experimental group scores compared to the control group may be due to yoga acting on reduced pain, fatigue, sleep, and mobility.

The psychological domain has shown improvement in the yoga group compared to control in all the facets like learning, feelings, spirituality, thinking, self-esteem, and memory. This improvement may be due to reduced stress, anxiety, and depression.[29]

The social domain scores are better in the yoga intervention group than the control group of enhanced interpersonal relationships and social support in the PTB patients. In contrast to this in the environmental domain, we observed no significant change in both groups, as the home environment remained the same throughout; this might have been the reason.

There have been a limited number of randomized controlled trials examining the effects of yoga on QoL in patients with PTB. One study published in 2018 in the reputed international journal found that a 12-week yoga intervention led to significant improvements in QoL, as well as reductions in anxiety and depression symptoms, among TB patients in India.

The study being Randomized controlled trial (RCT) design had more strength in terms of yoga addressing psychological issues, noninvasive, cost-effective, and easy to learn and practice. It is the first interventional study with yoga that had addressed the health-related aspects of QoL in PTB. However, few limitations are essential to note that this study had a small sample size, single district covered, study duration was not assessed in the continuation phase of TB treatment, and further research with higher sample size is needed to confirm these findings.

Conclusion

The study provides evidence to support the use of yoga as a complementary therapy for the NTEP in patients with PTB to improve their QoL. By enhancing QoL and respiratory function, yoga may help patient's better cope with TB's physical and psychological challenges, ultimately leading to better treatment outcomes and a better QoL.

Future suggestions

More research is needed to confirm these findings with large sample sizes, multicentric trials, different parameters, and types of yoga for patients with PTB. However, with appropriate care and support, many patients can manage their symptoms and achieve a good QoL. Hence, the yoga module may be included in future NTEP programs for better patient care.

Ethical statement

The study was approved by the Institutional Ethics Committee of Sri Devaraj Urs Academy of Higher Education and Research with Approval Ref: SDUAHER/IEC/MJ/13/22-23.

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Conflicts of interest

There are no conflicts of interest.

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Review Article-02

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Yoga and Quality of Life in Pulmonary Tuberculosis Patients During COVID-19 and Post- COVID-19: A Narrative Review

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Abstract: COVID-19 is a new pandemic that causes severe respiratory and enormous mental sickness, ultimately resulting to diminished quality of life in both patients and the general population. Since Yoga is a kind of mind-body therapy, it may be used to treat mental illness and improve patients' quality of life (QOL). The purpose of this review is to assemble the data on the relationship between Yoga and QOL for people with pulmonary tuberculosis and COVID-19. After searching PubMed and Google Scholar, we found a small number of publications that met our inclusion criteria and decided to focus on them. To get these findings, we used a technique called narrative synthesis. We found 156 articles on Yoga and COVID-19 after doing an electronic search, however, after applying the field tag, that number was decreased to 39. The inclusion criteria then used this information to pick up the final group of 8 articles. In all, 26 articles were chosen from the 543 that were obtained using Boolean operators between COVID-19 and QOL. Health-Related Quality of Life may be low among people with PTB and COVID-19, according to a meta-analysis of research. Since yoga has been shown to enhance respiratory problems and mental health, it has the potential to play an important role in reducing the negative effects of the PTB and COVID-19 pandemic on patients' quality of life in terms of their health. As a result, Yoga has the potential to be an effective technique in the treatment, prevention, and rehabilitation of both COVID-19 and pulmonary tuberculosis.

Keywords: Yoga; COVID-19; Tuberculosis; Quality of Life; Pulmonary Tuberculosis; Post-COVID-19

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Introduction

COVID-19, or the newly discovered Corona virus illness, is the world's worst viral disease. COVID-19 wreaked havoc on the global population by rapidly spreading and producing an exponential increase in the number of new cases. The World Health Organization estimates that there have been 480,170,572 confirmed cases of COVID-19, with 6,124,396 fatalities. The great stress on mental health and therefore on quality of life (QOL) (Nobari *et al*., 2021; WHO Global tuberculosis report 2019) has been brought about by lockdown, social isolation, economic crisis, unemployment, loss of one or both parents and relatives, and financial strain on the patients.

Mycobacterium tuberculosis is the bacterium responsible for pulmonary TB and was expected to cause 1.5 million deaths globally by 2020 (Central TB Division report). It has infected one-fourth of the world's population and, of those infected, between 10 and 15 per cent will develop active TB at some point in their lives. In 2018, India was responsible for 27 Lakh new cases of tuberculosis, or 27% of the global total (India TB Report, 2020; Tuberculosis WF, 2021). Positive outcomes have been achieved with the NTEP (New National Tuberculosis Elimination Programme). The elimination of tuberculosis by 2025 is a lofty goal, and getting there will require overcoming obstacles including finding effective treatments, dealing with patients' mental health, and enhancing their ability to breathe (Aggarwal *et al*., 2013). Patients with tuberculosis will suffer from a low QOL and extreme levels of stress, anxiety, and depression (Pachi *et al*., 2013).

There is a synergistic relationship between the spread of COVID-19 and pulmonary tuberculosis, which makes it more difficult to isolate the two diseases (Dass *et al*., 2022). COVID-19 is a new pandemic that causes terrible respiratory and enormous mental disease, ultimately resulting to lower quality of life in patients, whereas TB has been around for millennia and is responsible for the majority of fatalities in the globe (Cramer *et al*., 2017). Patients with pulmonary tuberculosis who were affected by the COVID-19 pandemic report low QOL and decreased medication taking as a result of the pandemic. Since Yoga is a kind of mind-body therapy, it may aid in the reduction of mental health problems and the enhancement of quality of life for patients. This review aims at collating available evidence on Yoga and QOL in Pulmonary Tuberculosis during COVID-19.

Materials and Methods

The PubMed and Google scholar search was carried out using the keywords "Yoga," "COVID-19", "Pulmonary Tuberculosis," "PTB," "Tuberculosis," "TB," "Quality of Life," "QOL," and their synonyms were used for electronic searching. A combination of different keywords used for searching on PubMed was searched for pertinent articles from search terms such as ["Pulmonary Tuberculosis" OR "PTB"], ["Tuberculosis" OR "TB"] ["Yoga" AND "COVID-19"], ["Yoga" AND "Pulmonary Tuberculosis"] AND ["COVID-19" AND "Quality of Life"] among them based on inclusion criterion – (i) Types of articles included were Randomized Control Trials, Clinical trials, Review articles, Systematic Reviews, and meta-analyses, (ii) Full-length free articles with robust methodology in the English language were included, (iii) Field tags used were titles and abstracts, (iv) Last 5 years' articles were picked, and(v) Reference lists of valid articles were searched for studies of similarity. The exclusion criterion is based on – (i) Articles with weak methodology and content, (ii) Case Reports and case series, (iii) Irrelevant topic of our interest. A narrative synthesis criterion was used to obtain the results.

Results and Discussion

After the electronic search, we got 156 articles related to Yoga and COVID-19, and with the field tags, it has reduced to 39 articles. Further on, the inclusion criterion was able to select full-length articles. Between Pulmonary Tuberculosis (PTB) and COVID-19, 71 articles among 8 articles were selected based on their relevance as shown in Figure 1. Using Boolean operators between Pulmonary Tuberculosis, COVID-19, and QOL able to get 543 articles; 25 research studies were picked after removing duplicates and exclusion

criteria. In the same way, between Yoga and Tuberculosis, we got only one article meeting the criterion. The many research studies were evaluated and found that PTB and COVID-19 patients may have a poor Health-Related Quality of Life.

Research Evidence in Yoga and COVID-19:

Research on the effects of yoga on the COVID-19 pandemic found that yoga (including physical postures, Bhramari Pranayama, mindfulness meditation, Sahaj yoga, and laughing therapy) had good impacts on mental health.

During the COVID-19 lockdown, volunteers took part in a randomized Control Trial that demonstrated the effectiveness of Viloma Pranayama in reducing RPE maximum during breath-holding. However, diaphragmatic breathing techniques greatly increase breath-holding duration (Visweswaraiah and Telles, 2004).

The study and practice of Sudarshana kriya include the use of certain breathing patterns and sequences. The autonomic nervous system's homeostasis is restored, and with it, stress, anxiety, depression, and stress-related disorders, are alleviated. The immune system is boosted, making the body better able to fend against many pathogens. During the COVID-19 epidemic, tele-yoga was shown to be helpful for both cancer patients and their caregivers.

In light of the possibility for future epidemics and pandemics involving novel illnesses, another study shows that yoga and meditation may help students manage with stress and maintain their health. Therefore, yoga will play an essential part in COVID-19 to improve the mental health status and general well-being of both healthy persons and those with illness.

Research in Yoga and Pulmonary Tuberculosis:

After two months, patients with PTB in the yoga and breath awareness group demonstrated asignificant improvement in symptom ratings (88.1%), weight gain (10.9%), forced vital capacity (FVC) (64.7%), and forced expiratory volume in one second (83.6%) (P <0.001 in all comparisons, Paired t-test). Lower symptom ratings (paired t-test, n=22) were seen in the breath awareness group. It is the only research done on Yoga and PTB in the last 20 years (Dalpati *et al*., 2022).

The co-infection of COVID-19 and pulmonary tuberculosis increases the likelihood of TB reactivation by influencing the respiratory system and generating acute illnesses through a cytokine-mediated immune response. Early identification of Tuberculosis among COVID-19 needed based on symptoms, CXR, and sputum test is crucial because of the high prevalence of active PTB among SARS-CoV-2 infected patients. For this to be a reality, the health care system must implement the required policies and infrastructure to prevent and treat co-infection. Corona virus-induced immune suppression, although complicating TB diagnosis and therapy, is a tough factor. More randomized controlled trials (RCTs) with high-quality methods and relevant material are urgently needed to address the special syndemic relationship between COVID-19 and PTB. In the highly specialized fields, only case reports indicate really exceptional cases.

Quality of Life (QOL) in Pulmonary Tuberculosis:

Due to increased psychological distress and reduced QOL in PTB patients, governmental and non-governmental organizations are now required to address psychological issues in TB therapy. Poor economic, physical, psychological, and environmental factors are only some of the reasons why persons with pulmonary TB have a far worse quality of life than the general population.

There are significant knowledge gaps concerning PTB patients' health-related quality of life (HRQOL), including in the areas of treatment adherence, mental health care integration, social support, and safety (Umesh *et al*., 2021).

Table1: Yoga and COVID-19

S. No.	Author and Publication	Study design	Sample size	Participants	Results	Findings
1	Kulkarni *et al.* (2021)	Meta-Analysis	NA	Children, youth and adults	The results of the review indicate moderate to positive effects of yoga on the mental health parameters.	Practicing yoga (physical postures, Bhramari Pranayam, mindfulness meditation, sahaj yoga and laughter therapy) can be beneficial to improve psychological health of the people during the COVID-19 pandemic.
2	Umesh *et al.* (2021)	Narrative Review	NA	Healthcare workers	The available evidences point towards the potential role of Yoga and *Ayurveda* in preventing and mitigating the infection through modulating our immune system, strengthening respiratory system, and mental health respectively.	Suggests an urgent need for conducting systematic clinical trials to investigate the add-on efficacy of *Yoga* and *Ayurveda* lifestyle interventions with current conventional treatment approaches.
3	Zope *et al.* (2021)	Narrative Review	NA	Healthy Volunteersand Patients	Sudharsana Kriya Yoga (SKY) balances the autonomic nervous system and thus can alleviate anxiety, routine stress, depression, stress-related medical disorders, and posttraumatic stress. SKY increase natural host immune system helps to tackle the microbial infections.	Article provides an overview of increases the therapeutic benefits that SKY can offer to the population at large during COVID-19 pandemic.
4	Dalpati *et al.* (2022)	Review	NA	Students	Perspectives shared in the review will also bring awareness on how yoga and meditation could boost students' performance and assist them in maintaining physical and mental wellbeing during stressful conditions such as future epidemics and pandemics with novel infections.	Adding regular yogic practices and other self-improvement routines to students' academic curriculum and daily practices in co-curricular activities or proficiency programs could help the younger generation take up the day-to-day challenges and stressful situations like lockdowns and pandemics and succeed in their personal and professional life.
5	Shukla *et al.* (2020_	RCT	60	Healthy volunteers	Anuloma Viloma Pranayama(AVP) and Deep Breathing Exercises(DBE) decreased Rating of Perceived Exertion (RPE). Kapala Bhati Pranayama(KBE) and pursed-lip breathing(PLB) did not decrease RPE as compare d to AVP and DBE. DBE increased BHT more than KBP and PLB interventions .	AVP reduces RPE maximally during breath-holding, whereas DPE increases BHT more.
6	Snyder *et al.* (2021)	RCT	14	Female caregivers of Cancer	Out of 7 dyads participating in the parent trial, 1 declined the video-conference	Although in-person interventions are favored by both the study

				Patients	sessions. Despite challenges in the areas of technology, location, and setting, instruction and personal connection, the overall acceptability was high among patients, caregivers, and instructors.	participants and the interventionists, videoconference sessions were deemed acceptable. All participants had the benefit of a previous in-person experience. In a remote setting, the assistance of caregivers seems particularly beneficial to ensure practice safety.
7	Shah *et al.* (2022)	Review and Meta-Analysis of RCT's	4023	Clinical, Pregnant and Healthy Population	Out of 174 they have selected 44 articles	Yoga,Meditation and Pranayama has very much effective in lowering IL-6, cortisol, and TNF-α levels in patients, long term practice of Yoga, spanned over 8–12 weeks will have definitive results in COVID-19 patients.

Table 2: Pulmonary Tuberculosis (PTB) and COVID-19

S. No.	Authors	Study design	Sample size	Participants	Findings
1	Aggarwal *et al.* (2021)	Systematic review and meta-analysis	236,863	COVID-19 and PTB Patients	Active pulmonary tuberculosis is relatively common among COVID-19 patients.
2	Siranart *et al.* (2023)	Cross-sectional cohort study	12,275 COVID-19 patients 26 having MTB	COVID-19 and PTB Patients	Early detection of Tuberculosis among Covid-19 required based on symptoms, CXR and sputum test.
3	Singh *et al.* (2020)	Review	157	TB&COVID-19 Confected patients	Health authorities should made necessary policies & facilities to fight & control against co-infection
4	Starshinova *et al.* (2022)	Review	--	*M. tuberculosis* Bacteria and SARS-CoV-2 Virus	Immune suppression caused by the Corona virus may result in difficulties in the diagnosis and treatment of TB.

Table 3: Pulmonary Tuberculosis (PTB) and Quality of Life

S. No.	Authors	Study design	Sample size	Participants	Findings
1	Zuo *et al.* (2022)	RCT	461	PTB Patients	Cognitive Behavioral Therapy can relieve anxiety, and depression symptoms and increase the quality of life in subjects with pulmonary tuberculosis.
2	Grass *et al.* (2022)	Pilot study	67	PTB Patients	The outcome of the study provides motivation for further consideration and implementation of a pulmonary rehabilitation programme for patients with PTB.
3	Xu *et al.* (2022)	RCT	150	PTB patients	Comprehensive nursing intervention combined with respiratory functional exercises can significantly improve the pulmonary function, self-care ability, and quality of life of patients with pulmonary

					tuberculosis, with obvious clinical efficacy.
4	Kumar *et al.* (2022)	RCT	46	PTB patients	Personalized dietary counselling was found to have a positive impact on BMI, total protein, and albumin levels in the experimental group, especially in underweight individuals. Besides, the quality of life measured using SGRQ.

Table 4: Research evidence for Quality of Life and COVID-19

S. No.	Authors	**Participants**	**Study design**	**Sample size**	**QoL Assessment**	**Result**	**Conclusion**
1	Nobari *et al.* (2021)	Children and adolescents.	Systematic review	3177	Health-Related Quality of life (HRQoL) were extracted from eligible studies.	Finally, six studies fulfilled the inclusion criteria and, therefore, were included in the systematic review.	COVID-19 has a negative impact on the HRQoL of children and/or adolescents.
2	Malik *et al.* (2022)	Post-acute COVID-19 syndrome (PCS) patients and intensive care unit (ICU) admitted cases.	Meta-Analysis	4828	Quality of life (EQ-VAS)	Meta-regression analysis showed the poor quality of life was significantly higher among post-COVID-19 patients.	Study concludes that PCS is associated with poor quality of life, persistent symptoms including fatigue, dyspnea, anosmia, sleep disturbances, and worse mental health
3	Amdal *et al.* (2021)	Active COVID-19 or Post-COVID-19 Patients	Systematic review	3342	To retrieve new publications on HRQoL issues including issues related to the long-term consequences of COVID-19.	The wide range of HRQoL issues experienced by patients with COVID-19.	The results provided the foundation for the international development of a COVID-19 specific patient-reported HRQoL questionnaire.
4	Dorri *et al.* (2021)	COVID-19 survivors.	Meta-Analysis	Varied 58-44779	A systematic search using key terms COVID-19, PTSD, depression, anxiety, HRQoL, survivors.	The pooled prevalence of PTSD, depression, and anxiety among COVID-19 survivors to pre-COVID-19 time and controls showed reduced HRQoL (RE).	Our systematic review also found evidence of reduced HQOL and limited social role in these survivors.
5	Ariyo *et al.* (2021)	Elderly intensive care unit (ICU) survivors .	Meta-Analysis	2536	Assessed quality of life (QoL) in ICU survivors before the COVID-19 pandemic.	Reduced quality of life due to physical health	Elderly survivors' QoL was significantly worse than younger ICU survivors
6	Kandula and Wake (2021)	Among Health Professionals	Review	Varies 170-10516	Assessment of the quality of life (QoL) of health professionals	QoL maintained by specific types of health professionals during critical moments of COVID-19 pandemics.	This study may assist health organization stakeholders in enhancing QoL among health professionals by required provisions.

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7	Poudel *et al.* (2021)	Acute Covid, females, older ages.	Structured Review	1276	Studies used a generic HRQoL assessment tool; five studies used SF-36, five studies used EQ-5D-5L.	After reading full-text, 12 eligible studies were included in this review. Higher impact on HRQoL was reported.	The impact of Covid-19 on HRQoL of Acute and Long Covid patients is substantial.
8	Nandasena *et al.* (2022)	COVID-19 patients following discharge or recovery.	Systematic review	4408	The Databases of PubMed, Cochrane Library, and Science Direct were searched.	COVID 19 patients' QOL has been significantly impacted and associated with the low level of QOL.	The QOL of the post COVID19 patients was significantly impacted, regardless of the time discharge or recovery.
9	Kasar and Karaman (2021)	Elderly individual.	Scoping Review		Assessing QoL	Resulted in seven studies selected for full reading, including three descriptive and cross-sectional studies.	Recommendations were grouped as evaluating the current state of loneliness and isolation in elderly people QOL negatively impacted.

Quality of Life (QOL) in COVID-19:

Children and adolescents with COVID-19 have a worse HRQoL (Shah *et al.*, 2022). According to the findings, those suffering with Post COVID-19 Syndrome(PCS) have a worse quality of life and have chronic symptoms such as tiredness, dyspnea, anosmia, sleep problems, and impaired mental health. More study on PCS patients is required to identify the underlying causes of this symptom and the subsequent decline in quality of life (Dorri *et al.*, 2021).

The varied HRQoL issues experienced by COVID-19 participants were the focus of this investigation. It exemplifies the catastrophic results of the illness. It is very essential because it helps doctors spot the illness earlier and equips them with the knowledge to prevent future outbreaks. The findings provide a foundation for the global creation of a patient-reported HRQoL questionnaire tailored to people with COVID-19 (Zuo *et al.*, 2022).

Many patients who survived COVID-19 may have post-traumatic stress disorder (PTSD), despair, and anxiety beyond the first month of recovery. New data reveals that these survivors have worse HQOL and play a less social role than previously thought.

Subjective QOL outcomes should guide person-centered decision-making in senior ICU patients (Amdal *et al.*, 2021), and it is important to keep an eye on the proportionality of age as a factor of ICU resource allocation.

The quality of life (QoL) of COVID-19 patients has been shown to decline, according to many studies; researchers should take into account the most significantly impacted QoL domains and related variables..

Conclusion

Yoga may be an add-on therapy as it improves respiratory conditions and mental health; hence it may play vital role as preventative, curative and rehabilitation role in PTB and COVID-19 pandemic by improving Health-related quality of life.

There is a need for evidence-based research with more emphasis should be given to Randomized Control Trails in Yoga, Pulmonary Tuberculosis and COVID-19 as well as in Post-COVID-19. Yoga can act At the government level further adding the new policies adopting to the new pandemic era required to enhance the quality of life.

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APPENDIX I-B

Presentations from Ph.D. Work

1. Presented a paper at International Conference- YANTRA-2023 and Received the "**Best Oral Presentation Award"** for the paper entitled "*A Randomized Control Trial to Evaluate the effect of Integrated Yoga on Depression in Patients with Pulmonary Tuberculosis*" organized by **National Institute of Mental Health and Neurosciences-NIMHANS**, associated with Ministry of AYUSH, and Jignasa held on 24th&25th November 2023

Yantra
Yoga & Ayurveda in Neurosciences Therapeutic & Research Approaches 2023

International Conference on
Integrative Medicine
Theme: Models of Integration in Health Care

23-25 November 2023
NIMHANS Convention Centre, Bengaluru, India

National Institute of Mental Health and Neuro Sciences | Jignasa जिज्ञासा | TSST | Ministry of AYUSH Government of India

@jignasaayush www.jignasa.in Official 'Jignasa' App

CERTIFICATE OF APPRECIATION

Best Oral Presentation

This is to acknowledge and express our sincere appreciation to

✓ Dr/Sri/Smt/Kum. SRINIVAS M

of

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION, KOLAR

for his/her outstanding achievement in

Winning IIIrd prize for the Best Oral Presentation at the International Conference YANTRA – 2023 on Models of Integration in Health Care held from 23rd to 25th November 2023 at NIMHANS Convention Centre, Bengaluru, India.

Dr. Shivarama Varambally
Organising Chairperson
Yantra -2023

Dr. Kishore Kumar
Organising Secretary
Yantra- 2023

Dr. S. Ramchandra Setty
President,
TSST

Dr. Sachin Singh Basera
National Convenor,
Jignasa

2. Presented a paper at National Conference- **Pulmonary Rehabilitation-2023** and received a "**Best Scientific Presentation Award"** for the paper entitled *"Effect of integrated Yoga on patients with Pulmonary Tuberculosis: A Randomized Controlled Trial*" organized by **Sri Devaraj Urs Medical College**, Kolar associated with Karnataka Medical Council (KMC) and Indian Association of Respiratory Care (IARC) held on 22nd December 2023.

APPENDIX II-A

PROFORMA

Demographic Profile:

Name: _____

Hospital IP/OP number: _____

Age/Sex: _____ Marital Status: married/ Unmarried/Divorced

Residential address: _____

_____

Mobile no: _____ Alternate No:

E-mail ID: _____

Occupation: _____ Locality: Urban/ Semi-Urban/ Rural

Educational status: _____

Case History:

Other known Illness:

General Parameters:

Weight: _____ Height: _____BMI: _____SpO2_____

Clinical Examination:

Sputum Test: Diagnosis of PTB: Clinically/Microbiologically

Sputum Culture:

Chest X-Ray:

Clinical Symptoms:

Clinical symptoms	**Baseline**	**8th week**	**24th week**
Fever			
Cough with expectoration			
Loss of Weight			
Loss of Appetite			
Weakness			
General health condition			

Signature of Investigator(s):

Ph.D. Scholar **Co-Supervisor** **Supervisor**

1._____ 2. _____3._____

Parameters Analysis:

I. Pulmonary Function Test (PFT):

PFT Values	**Baseline (Pre)**	**8th Week (Post)**
FEV1		
FVC		
Ratio of FEV1/FVC		

II. WHO BREF- Health Related Quality of Life (HRQOL) Questionnaire:

Domains Scores	**Baseline (Pre)**	**8th Week (Post)**
Physical health		
Psychological		
Social relationships		
Environment		
Total Scores		

III. Hamilton Depression Rating Scale (HDRS) Questionnaire:

HDRS Range Scores	**Baseline (Pre)**	**8th Week (Post)**
Normal (0-7)		
Mild Depression (8-16)		
Moderate Depression (17-23)		
Severe Depression (Over 24)		
Total Scores		

APPENDIX II-B

Patient Information Sheet

Title of the study: - "Effect of Integrated Yoga as an adjuvant therapy to standard care in Pulmonary Tuberculosis-A Randomized Control Trial"

Introduction

You are being invited to take part in a research study. Before you decide to participate or not, it is important for you to understand why this research is being carried out and your role in the project. Please take time to read the following information carefully and discuss it with your friends, relatives and your treating physician/family doctor if you wish before you take the decision to participate or not in this study. Don't hesitate to ask us if there is anything that is not clear here or for more information. Take as much time as you need to decide whether or not to participate in this study.

What is the purpose of the study?

The purpose of the study is to assess the effect of integrated Yoga as an adjuvant therapy to National Tuberculosis Elimination Programme (NTEP) by evaluating pulmonary function test (PFT), health related quality of life (HRQOL), and depression among patients with Pulmonary Tuberculosis.

Background

Tuberculosis is the most common and oldest infectious disease in the world. India is a leading contributor in terms of number of incidence cases in the world. Pulmonary Tuberculosis is the most common type of tuberculosis which affects the lung and causes difficulty in breathing, cough, tiredness and loss of appetite. So, Yoga is a great tool as an add-on therapy as it will help in improving lung capacity, health related quality of life, decreases depression along with the standard care of the National Tuberculosis Elimination Programme (NTEP).

Why have you been chosen?

The study is on the persons who have pulmonary tuberculosis and who are visiting RL Jalappa Hospital and Research Center, Tamaka Kolar district is the location of the study. Based

on the subject selection criteria of the present study (participants between 18 - 60 years), we invite you to participate in the study.

Do you have to take part?

Your participation in this research work is entirely voluntary. It is your choice whether to participate or not. It is not necessary that you must participate in the study. It is entirely up to you to decide. You will be given a copy of this information sheet and have adequate time to read through this, think and ask any questions before making a decision. If you do decide to take part you will be asked to sign a consent form (a copy of which will also be given to you). If you decide to take part, you are still free to withdraw at any time during the study without giving any reason. A decision not to take part or to withdraw from the study whenever you choose, will not affect your right or entitlement for your standard medical care that you may need.

What is your role in this project?

After an information session and providing written informed consent to Dept. of Integrative Medicine for assessments. Initially, we would like to ask you some questions, get some details regarding your history, general health, work, lifestyle etc. which will be followed by Yoga intervention will be given for experimental/study group for 45 minutes per day and have to do as per the instructions by the Yoga trained instructor. Please note that irrespective of whether you are included or not included in the study, your treatment aspect will not be affected if you do not wish to participate.

The list of tests to be conducted includes the following:

- **Pulmonary Function Test (PFT):** Pulmonary Function Tests (PFT's) are group of non-invasive tests that shows the how well your lungs works, how lungs take in and exhale air, and how efficiently they transfer oxygen into blood. The PFT's usually measure lung volume, lung capacity, rates of flow, and gas exchange. PFT's useful in measuring the functional status of the respiratory system both physiological and pathophysiological condition. We will evaluate the
    - Forced Vital Capacity (FVC)- patient is exhaling at maximal speed and effort,
    - Forced Expiratory Volume in 1 second (FEV1)- expiratory volume in 1 seconds from a position of full inspiration and
    - Ratio of FEV1/FVC will be tested using spirometry.

- **Health Related Quality Of Life (HRQOL):** The health related quality of the life is a person's overall quality of life that represents the functional effect of illness and its consequent therapy upon a patient, as perceived by the patient. HRQOL will be assessed using a WHOQOL-BREF questionnaire in the baseline and end of the 24 weeks of the study. WHOQOL-BREF questionnaire consists of 26 items which provides information regarding 4 broad domains such as Physical health, Psychological health, Social Relationships, Environment. For those who cannot read and write, for them we will ask questions personally and get the information.
- **Depression:** psychological stress refers to abnormal condition due to mental stress/strain. In the present scenario we are concentrating on depression, as it is a one of the major factor that can be often seen in tuberculosis patients. Here we are observing comorbid depression in TB patient, and it is addressing through the **Hamilton Depression Rating Scale (HDRS**) questionnaire consists of 17 items and 0-4 scaling range. The clinician will ask questions personally to the participant and get the information.

What is the duration of Yoga intervention?

Total duration of the Yoga therapy is 45 minutes per day/ 5 days a week and 8 weeks in total. In 24 weeks, 12 weeks of Yoga instruction and 12 weeks follow up will be done.

What are the benefits of undergoing the Yoga intervention?

- By participating in this research you will benefit by improved levels of Pulmonary Functions/lung parameters,
- Improved levels of infections,
- Improvement in Health Related Quality of Life (HRQOL)
- Decreased level of depression and Anxiety.
- Faster sputum conversion rates,
- Improvement in Physical strength and decrease in the stress levels.
- Your participation will also help us to use the outcomes of this study for future subjects.
- The participants are not entitled for any monetary or other benefits for participating in the study.

Are there risks involved in undergoing these tests?

All these tests are non-invasive, totally safe and will not harm or irritate you in anyway. There are absolutely no risks or any inconvenience for participating in this study

As our study is non-invasive in nature your participation in this study will not put you at any risk but if you do beyond your capacity of stretching that may end up in sprain and pain.
If so happens you can contact principal investigator, so that you will be provided required care/ treatment at the right time.

Cost of participation in the study

You will not be entitled to pay for the intervention or for the laboratory test during the study duration. You will not be paid for your participation in the research study.

Confidentiality of information

All data will be coded using unique identification numbers which will be known only to investigating team. Only this code will be indicated in all assessment sheets, so your identity will never be revealed to anyone. Your name will not be disclosed outside the hospital or appear on any reports or publications resulting from the study. The data generated from this research will be anonymous, with no indication of the identity of individuals involved. The results of the tests carried out, however, will be revealed and explained to you. A copy of the results will also be given to you.

What will happen to the samples (data) you have given?

The data obtained will be analyzed scientifically. The results obtained from this study may be published in scientific journals. Results may also be presented in scientific conferences /seminars. We will publish the results in order that other interested people may learn from our research.

Who is organizing the study?

The research is being conducted by Mr. Srinivas M, PhD scholar in the Department of Integrative Medicine under the guidance of Dr. Neetinakumar, Assoc. Professor, Department of Integrative Medicine at the Sri Devaraj Urs Academy of higher Education and Research, Tamaka, Kolar. And our co-guide Dr Jagmohan S V, Asst. Proffessor. , Department of Pulmonology at RL Jalappa Hospital and Research Center, Tamaka,

Who has reviewed this study?

The PhD doctoral Committee of the SDUHAER (Deemed to be University) has cleared the proposal for its scientific content; the study has been approved by the Central Ethics

Committee, Sri Devaraj Urs Academy of Higher Education and Research for the ethical aspects / standards.

If you need any more information about this study, you may please contact the following at any time of the study.

Mr. Srinivas M
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Dr Jagmohan S V
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APPENDIX II-B

PATIENTS INFORMATION SHEET IN KANNADA VERSION

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ: - "ಶ್ವಾಸಕೋಶದ ಕ್ಷಯರೋಗದಲ್ಲಿ ಪ್ರಮಾಣಿತ ಆರೈಕೆಗೆ ಸಹಾಯಕ ಚಿಕಿತ್ಸೆಯಾಗಿ ಸಂಯೋಜಿತ ಯೋಗದ ಪರಿಣಾಮ- ಒಂದು ಯಾದೃಚ್ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗ"

ಪರಿಚಯ

ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಿಮ್ಮನ್ನು ಆಹ್ವಾನಿಸಲಾಗುತ್ತಿದೆ. ಭಾಗವಹಿಸಲು ಅಥವಾ ಬೇಡವೆಂದು ನೀವು ನಿರ್ಧರಿಸುವ ಮೊದಲು, ಈ ಸಂಶೋಧನೆಯನ್ನು ಏಕೆ ನಡೆಸಲಾಗುತ್ತಿದೆ ಮತ್ತು ಯೋಜನೆಯಲ್ಲಿ ನಿಮ್ಮ ಪಾತ್ರವನ್ನು ನೀವು ಅರ್ಥಮಾಡಿಕೊಳ್ಳುವುದು ಬಹಳ ಮುಖ್ಯ. ದಯವಿಟ್ಟು ಈ ಕೆಳಗಿನ ಮಾಹಿತಿಯನ್ನು ಎಚ್ಚರಿಕೆಯಿಂದ ಓದಲು ಸಮಯ ತೆಗೆದುಕೊಳ್ಳಿ ಮತ್ತು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅಥವಾ ಇಲ್ಲದಿರಲು ನೀವು ನಿರ್ಧಾರ ತೆಗೆದುಕೊಳ್ಳುವ ಮೊದಲು ನೀವು ಬಯಸಿದರೆ ನಿಮ್ಮ ಸ್ನೇಹಿತರು, ಸಂಬಂಧಿಕರು ಮತ್ತು ನಿಮ್ಮ ಚಿಕಿತ್ಸೆ ನೀಡುವ ವೈದ್ಯ / ಕುಟುಂಬ ವೈದ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಇಲ್ಲಿ ಸ್ಪಷ್ಟವಾಗಿಲ್ಲ ಅಥವಾ ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಏನಾದರೂ ಇದೆಯೇ ಎಂದು ನಮ್ಮನ್ನು ಕೇಳಲು ಹಿಂಜರಿಯಬೇಡಿ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಬೇಕೆ ಅಥವಾ ಬೇಡವೇ ಎಂಬುದನ್ನು ನೀವು ನಿರ್ಧರಿಸುವಷ್ಟು ಸಮಯ ತೆಗೆದುಕೊಳ್ಳಿ.

ಅಧ್ಯಯನದ ಉದ್ದೇಶವೇನು?

ಪಲ್ಮನರಿ ಫಂಕ್ಷನ್ ಟೆಸ್ಟ್ (ಪಿಎಫ್‌ಟಿ), ಆರೋಗ್ಯ ಸಂಬಂಧಿತ ಜೀವನದ ಗುಣಮಟ್ಟ (ಎಚ್‌ಆರ್‌ಕ್ಯುಒಎಲ್) ಮತ್ತು ಶ್ವಾಸಕೋಶದ ಕ್ಷಯ ರೋಗಿಗಳಲ್ಲಿ ಖಿನ್ನತೆಯನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡುವ ಮೂಲಕ ರಾಷ್ಟ್ರೀಯ ಕ್ಷಯರೋಗ ಎಲಿಮಿನೇಷನ್ ಪ್ರೋಗ್ರಾಂ (ಎನ್‌ಟಿಇಪಿ) ಗೆ ಸಹಾಯಕ ಚಿಕಿತ್ಸೆಯಾಗಿ ಸಂಯೋಜಿತ ಯೋಗದ ಪರಿಣಾಮವನ್ನು ನಿರ್ಣಯಿಸುವುದು ಅಧ್ಯಯನದ ಉದ್ದೇಶವಾಗಿದೆ. .

ಹಿನ್ನೆಲೆ

ಕ್ಷಯರೋಗವು ವಿಶ್ವದ ಅತ್ಯಂತ ಸಾಮಾನ್ಯ ಮತ್ತು ಹಳೆಯ ಸಾಂಕ್ರಾಮಿಕ ಕಾಯಿಲೆಯಾಗಿದೆ. ವಿಶ್ವದ ಘಟನೆಗಳ ಸಂಖ್ಯೆಯಲ್ಲಿ ಭಾರತವು ಪ್ರಮುಖ ಕೊಡುಗೆ ನೀಡಿದೆ.

ಶ್ವಾಸಕೋಶದ ಕ್ಷಯವು ಕ್ಷಯರೋಗದ ಅತ್ಯಂತ ಸಾಮಾನ್ಯ ವಿಧವಾಗಿದ್ದು, ಇದು ಶ್ವಾಸಕೋಶದ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುತ್ತದೆ ಮತ್ತು ಉಸಿರಾಟ, ಕೆಮ್ಮು, ದಣಿವು ಮತ್ತು ಹಸಿವಿನ ಕೊರತೆಯನ್ನು ಉಂಟುಮಾಡುತ್ತದೆ. ಆದ್ದರಿಂದ ಯೋಗವು ಪೂರಕ ಚಿಕಿತ್ಸೆಯಾಗಿ ಒಂದು ಉತ್ತಮ ಸಾಧನವಾಗಿದ್ದು, ಇದು ಶ್ವಾಸಕೋಶದ ಸಾಮರ್ಥ್ಯ, ಆರೋಗ್ಯ ಸಂಬಂಧಿತ ಜೀವನದ ಗುಣಮಟ್ಟವನ್ನು ಸುಧಾರಿಸಲು ಸಹಾಯ ಮಾಡುತ್ತದೆ, ಖಿನ್ನತೆಯನ್ನು ಕಡಿಮೆ ಮಾಡುತ್ತದೆ ಮತ್ತು ರಾಷ್ಟ್ರೀಯ ಕ್ಷಯರೋಗ ನಿರ್ಮೂಲನೆ ಕಾರ್ಯಕ್ರಮದ (ಎನ್‌ಟಿಇಪಿ) ಪ್ರಮಾಣಿತ ಆರೈಕೆಯೊಂದಿಗೆ ಸಹಾಯ ಮಾಡುತ್ತದೆ.

ನಿಮ್ಮನ್ನು ಏಕೆ ಆಯ್ಕೆ ಮಾಡಲಾಗಿದೆ?

ಶ್ವಾಸಕೋಶದ ಕ್ಷಯರೋಗ ಹೊಂದಿರುವ ಮತ್ತು ತಮಕಾ ಕೋಲಾರ ಜಿಲ್ಲೆಯ ಆರ್.ಎಲ್. ಜಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರಕ್ಕೆ ಭೇಟಿ ನೀಡುತ್ತಿರುವ ವ್ಯಕ್ತಿಗಳ ಮೇಲೆ ಈ ಅಧ್ಯಯನ ನಡೆಯುತ್ತಿದೆ. ಪ್ರಸ್ತುತ ಅಧ್ಯಯನದ ವಿಷಯ ಆಯ್ಕೆ ಮಾನದಂಡಗಳ ಆಧಾರದ ಮೇಲೆ (ಭಾಗವಹಿಸುವವರು 18 ರಿಂದ 60 ವರ್ಷಗಳು), ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನಾವು ನಿಮ್ಮನ್ನು ಆಹ್ವಾನಿಸುತ್ತೇವೆ.

ನೀವು ಭಾಗವಹಿಸಬೇಕೇ?

ಈ ಸಂಶೋಧನಾ ಕಾರ್ಯದಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆ ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ. ಭಾಗವಹಿಸಬೇಕೆ ಅಥವಾ ಬೇಡವೇ ಎಂಬುದು ನಿಮ್ಮ ಆಯ್ಕೆಯಾಗಿದೆ. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದು ಅನಿವಾರ್ಯವಲ್ಲ. ನಿರ್ಧರಿಸಲು ಇದು ಸಂಪೂರ್ಣವಾಗಿ ನಿಮ್ಮದಾಗಿದೆ. ನಿಮಗೆ ಈ ಮಾಹಿತಿ ಹಾಳೆಯ ಪ್ರತಿಯನ್ನು ನೀಡಲಾಗುವುದು ಮತ್ತು ಈ ಮೂಲಕ ಓದಲು, ನಿರ್ಧಾರ ತೆಗೆದುಕೊಳ್ಳುವ ಮೊದಲು ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಮತ್ತು ಕೇಳಲು ಸಾಕಷ್ಟು ಸಮಯವನ್ನು ಹೊಂದಿರುತ್ತೀರಿ. ನೀವು ಭಾಗವಹಿಸಲು ನಿರ್ಧರಿಸಿದರೆ ಒಪ್ಪಿಗೆ ಪತ್ರಕ್ಕೆ ಸಹಿ ಹಾಕುವಂತೆ ನಿಮ್ಮನ್ನು ಕೇಳಲಾಗುತ್ತದೆ (ಅದರ ನಕಲನ್ನು ಸಹ ನಿಮಗೆ ನೀಡಲಾಗುವುದು). ನೀವು ಭಾಗವಹಿಸಲು ನಿರ್ಧರಿಸಿದರೆ ನೀವು ಯಾವುದೇ ಕಾರಣವನ್ನು ನೀಡದೆ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ನೀವು ಆಯ್ಕೆ ಮಾಡದಿದ್ದಾಗ ಭಾಗವಹಿಸದಿರಲು ಅಥವಾ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯುವ ನಿರ್ಧಾರವು ನಿಮಗೆ ಅಗತ್ಯವಿರುವ ನಿಮ್ಮ ಪ್ರಮಾಣಿತ ವೈದ್ಯಕೀಯ ಆರೈಕೆಗಾಗಿ ನಿಮ್ಮ ಹಕ್ಕು ಅಥವಾ ಅರ್ಹತೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.

ಈ ಯೋಜನೆಯಲ್ಲಿ ನಿಮ್ಮ ಪಾತ್ರವೇನು?

ಮಾಹಿತಿ ಅಧಿವೇಶನದ ನಂತರ ಮತ್ತು ಮೌಲ್ಯಮಾಪನಗಳಿಗಾಗಿ ಇಂಟಿಗ್ರೇಟಿವ್ ಮೆಡಿಸಿನ್ ಇಲಾಖೆಗೆ ಲಿಖಿತ ತಿಳುವಳಿಕೆಯ ಒಪ್ಪಿಗೆಯನ್ನು ಒದಗಿಸುವುದು. ಆರಂಭದಲ್ಲಿ, ನಾವು ನಿಮಗೆ ಕೆಲವು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಬಯಸುತ್ತೇವೆ, ನಿಮ್ಮ ಇತಿಹಾಸ, ಸಾಮಾನ್ಯ ಆರೋಗ್ಯ, ಕೆಲಸ, ಜೀವನ ಶೈಲಿ ಇತ್ಯಾದಿಗಳ ಬಗ್ಗೆ ಕೆಲವು ವಿವರಗಳನ್ನು ಪಡೆದುಕೊಳ್ಳುತ್ತೇವೆ, ನಂತರ ಯೋಗ ಹಸ್ತಕ್ಷೇಪವನ್ನು ಪ್ರಾಯೋಗಿಕ / ಅಧ್ಯಯನ ಗುಂಪಿಗೆ ದಿನಕ್ಕೆ 60 ನಿಮಿಷಗಳ ಕಾಲ ನೀಡಲಾಗುವುದು ಮತ್ತು ಮಾಡಬೇಕಾಗುತ್ತದೆ ಯೋಗ ತರಬೇತಿ ಪಡೆದ ಬೋಧಕರ ಸೂಚನೆಯಂತೆ ಮಾಡಿ. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲ್ಪಟ್ಟಿದ್ದೀರಾ ಅಥವಾ ಸೇರಿಸಲಾಗಿಲ್ಲವೇ ಎಂಬುದನ್ನು ಲೆಕ್ಕಿಸದೆ, ನೀವು ಭಾಗವಹಿಸಲು ಇಚ್ do ಿಸದಿದ್ದರೆ ನಿಮ್ಮ ಚಿಕಿತ್ಸೆಯ ಅಂಶವು ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.

ನಡೆಸಬೇಕಾದ ಪರೀಕ್ಷೆಗಳ ಪಟ್ಟಿ ಈ ಕೆಳಗಿನವುಗಳನ್ನು ಒಳಗೊಂಡಿದೆ:

ಶ್ವಾಸಕೋಶದ ಕಾರ್ಯ ಪರೀಕ್ಷೆ (ಪಿಎಫ್‌ಟಿ): ಶ್ವಾಸಕೋಶದ ಕಾರ್ಯ ಪರೀಕ್ಷೆಗಳು (ಪಿಎಫ್‌ಟಿ) ಆಕ್ರಮಣಶೀಲವಲ್ಲದ ಪರೀಕ್ಷೆಗಳ ಗುಂಪಾಗಿದ್ದು ಅದು ನಿಮ್ಮ ಶ್ವಾಸಕೋಶಗಳು ಎಷ್ಟು ಚೆನ್ನಾಗಿ ಕಾರ್ಯನಿರ್ವಹಿಸುತ್ತವೆ, ಶ್ವಾಸಕೋಶಗಳು ಗಾಳಿಯನ್ನು ಹೇಗೆ ತೆಗೆದುಕೊಳ್ಳುತ್ತವೆ ಮತ್ತು ಉಸಿರಾಡುತ್ತವೆ ಮತ್ತು ಅವು ಆಮ್ಲಜನಕವನ್ನು ರಕ್ತಕ್ಕೆ ಎಷ್ಟು ಪರಿಣಾಮಕಾರಿಯಾಗಿ ವರ್ಗಾಯಿಸುತ್ತವೆ ಎಂಬುದನ್ನು ತೋರಿಸುತ್ತದೆ. ಪಿಎಫ್‌ಟಿಯು ಸಾಮಾನ್ಯವಾಗಿ ಶ್ವಾಸಕೋಶದ ಪ್ರಮಾಣ, ಶ್ವಾಸಕೋಶದ ಸಾಮರ್ಥ್ಯ, ಹರಿವಿನ ಪ್ರಮಾಣ ಮತ್ತು ಅನಿಲ ವಿನಿಮಯವನ್ನು ಅಳೆಯುತ್ತದೆ. ಶಾರೀರಿಕ ಮತ್ತು ರೋಗಶಾಸ್ತ್ರೀಯ ಸ್ಥಿತಿಯೆರಡನ್ನೂ ಉಸಿರಾಟದ ವ್ಯವಸ್ಥೆಯ ಕ್ರಿಯಾತ್ಮಕ ಸ್ಥಿತಿಯನ್ನು ಅಳೆಯಲು ಪಿಎಫ್‌ಟಿ ಉಪಯುಕ್ತವಾಗಿದೆ. ನಾವು ಈ ಕೆಳಗಿನವುಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡುತ್ತೇವೆ

ಬಲವಂತದ ವೈಟಲ್ ಸಾಮರ್ಥ್ಯ (ಎಫ್‌ವಿಸಿ) - ರೋಗಿಯು ಗರಿಷ್ಠ ವೇಗ ಮತ್ತು ಶ್ರಮದಿಂದ ಉಸಿರಾಡುತ್ತಿದ್ದಾನೆ,

1 ಸೆಕೆಂಡಿನಲ್ಲಿ ಬಲವಂತದ ಎಕ್ಸ್‌ಪಿರೇಟರಿ ವಾಲ್ಯೂಮ್ (ಎಫ್‌ಇವಿ 1) - ಪೂರ್ಣ ಸ್ಫೂರ್ತಿಯ ಸ್ಥಾನದಿಂದ 1 ಸೆಕೆಂಡುಗಳಲ್ಲಿ ಮುಕ್ತಾಯದ ಪರಿಮಾಣ ಮತ್ತು **ಎಫ್‌ಇವಿ 1 / ಎಫ್‌ವಿಸಿಯ ಅನುಪಾತ**ವನ್ನು ಸ್ಪಿರೋಮೆಟ್ರಿ ಬಳಸಿ ಪರೀಕ್ಷಿಸಲಾಗುತ್ತದೆ.

ಆರೋಗ್ಯ ಸಂಬಂಧಿತ ಜೀವನದ ಗುಣಮಟ್ಟ (HRQOL): ಆರೋಗ್ಯದ ಜೀವನದ ಗುಣಮಟ್ಟವು ವ್ಯಕ್ತಿಯ ಒಟ್ಟಾರೆ ಜೀವನದ ಗುಣಮಟ್ಟವಾಗಿದ್ದು, ಇದು ರೋಗಿಯ ಕ್ರಿಯಾತ್ಮಕ ಪರಿಣಾಮವನ್ನು ಮತ್ತು ರೋಗಿಯ ಮೇಲೆ ಅದರ ಪರಿಣಾಮಕಾರಿ ಚಿಕಿತ್ಸೆಯನ್ನು ಪ್ರತಿನಿಧಿಸುತ್ತದೆ. ಅಧ್ಯಯನದ 24 ವಾರಗಳ ಬೇಸ್‌ಲೈನ್ ಮತ್ತು ಕೊನೆಯಲ್ಲಿ WHOQOL-BREF ಪ್ರಶ್ನಾವಳಿಯನ್ನು ಬಳಸಿ HRQOL ಅನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ. WHOQOL-BREF ಪ್ರಶ್ನಾವಳಿಯು 26 ವಸ್ತುಗಳನ್ನು ಒಳಗೊಂಡಿದೆ, ಇದು ದೈಹಿಕ ಆರೋಗ್ಯ, ಮಾನಸಿಕ ಆರೋಗ್ಯ, ಸಾಮಾಜಿಕ ಸಂಬಂಧಗಳು, ಪರಿಸರ ಮುಂತಾದ 4 ವಿಶಾಲ ಡೊಮೇನ್‌ಗಳ ಬಗ್ಗೆ ಮಾಹಿತಿಯನ್ನು ಒದಗಿಸುತ್ತದೆ. ಓದಲು ಮತ್ತು ಬರೆಯಲು ಸಾಧ್ಯವಾಗದವರಿಗೆ, ಅವರಿಗೆ ನಾವು ವೈಯಕ್ತಿಕವಾಗಿ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುತ್ತೇವೆ ಮತ್ತು ಮಾಹಿತಿಯನ್ನು ಪಡೆಯುತ್ತೇವೆ.

ಖಿನ್ನತೆ: ಮಾನಸಿಕ ಒತ್ತಡ / ಒತ್ತಡದಿಂದಾಗಿ ಮಾನಸಿಕ ಒತ್ತಡವು ಅಸಹಜ ಸ್ಥಿತಿಯನ್ನು ಸೂಚಿಸುತ್ತದೆ. ಪ್ರಸ್ತುತ ಸನ್ನಿವೇಶದಲ್ಲಿ ನಾವು ಖಿನ್ನತೆಯತ್ತ ಗಮನ ಹರಿಸುತ್ತಿದ್ದೇವೆ, ಏಕೆಂದರೆ ಇದು ಕ್ಷಯ ರೋಗಿಗಳಲ್ಲಿ ಹೆಚ್ಚಾಗಿ ಕಂಡುಬರುವ ಪ್ರಮುಖ ಅಂಶವಾಗಿದೆ. ಇಲ್ಲಿ ಇಲ್ಲಿ ನಾವು ಟಿಬಿ ರೋಗಿಯಲ್ಲಿ ಕೊಮೊರ್ಬಿಡ್ ಖಿನ್ನತೆಯನ್ನು ಗಮನಿಸುತ್ತಿದ್ದೇವೆ ಮತ್ತು ಇದು ಹ್ಯಾಮಿಲ್ಟನ್ ಡಿಪ್ರೆಶನ್ ರೇಟಿಂಗ್ ಸ್ಕೇಲ್ (ಎಚ್‌ಡಿಆರ್ಎಸ್) ಪ್ರಶ್ನಾವಳಿಯ ಮೂಲಕ 17 ವಸ್ತುಗಳನ್ನು ಮತ್ತು 0-4 ಸ್ಕೇಲಿಂಗ್ ಶ್ರೇಣಿಯನ್ನು ಒಳಗೊಂಡಿದೆ. ವೈದ್ಯರು ಭಾಗವಹಿಸುವವರಿಗೆ ವೈಯಕ್ತಿಕವಾಗಿ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುತ್ತಾರೆ ಮತ್ತು ಮಾಹಿತಿಯನ್ನು ಪಡೆಯುತ್ತಾರೆ.

ಯೋಗ ಹಸ್ತಕ್ಷೇಪದ ಅವಧಿ ಎಷ್ಟು?

ಯೋಗ ಚಿಕಿತ್ಸೆಯ ಒಟ್ಟು ಅವಧಿ ದಿನಕ್ಕೆ 45 ನಿಮಿಷಗಳು / ವಾರದಲ್ಲಿ 5 ದಿನಗಳು ಮತ್ತು ಒಟ್ಟು 24 ವಾರಗಳು. 24 ವಾರಗಳಲ್ಲಿ 12 ವಾರಗಳ ಯೋಗ ಸೂಚನೆ ಮತ್ತು 12 ವಾರಗಳ ಫಾಲೋ ಅಪ್ ಮಾಡಲಾಗುತ್ತದೆ.

ಯೋಗ ಅಧ್ಯಯನಕ್ಕೆ ಒಳಗಾಗುವುದರಿಂದ ಏನು ಪ್ರಯೋಜನ?

- ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವ ಮೂಲಕ ನೀವು ಸುಧಾರಿತ ಮಟ್ಟದ ಶ್ವಾಸಕೋಶದ ಕಾರ್ಯಗಳು / ಶ್ವಾಸಕೋಶದ ನಿಯತಾಂಕಗಳಿಂದ ಪ್ರಯೋಜನ ಪಡೆಯುತ್ತೀರಿ,
- ಸೋಂಕಿನ ಸುಧಾರಿತ ಮಟ್ಟಗಳು,

- ಆರೋಗ್ಯ ಸಂಬಂಧಿತ ಜೀವನದ ಗುಣಮಟ್ಟದಲ್ಲಿ ಸುಧಾರಣೆ (HRQOL)
- ಖಿನ್ನತೆ ಮತ್ತು ಆತಂಕದ ಮಟ್ಟ ಕಡಿಮೆಯಾಗಿದೆ.
- ವೇಗವಾಗಿ ಕಫ ಪರಿವರ್ತನೆ ದರಗಳು,
- ದೈಹಿಕ ಸಾಮರ್ಥ್ಯದಲ್ಲಿ ಸುಧಾರಣೆ ಮತ್ತು ಒತ್ತಡದ ಮಟ್ಟದಲ್ಲಿನ ಇಳಿಕೆ.
- ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಈ ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ಭವಿಷ್ಯದ ವಿಷಯಗಳಿಗೆ ಬಳಸಲು ನಮಗೆ ಸಹಾಯ ಮಾಡುತ್ತದೆ.
- ಭಾಗವಹಿಸುವವರು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಯಾವುದೇ ವಿತ್ತೀಯ ಅಥವಾ ಇತರ ಪ್ರಯೋಜನಗಳಿಗೆ ಅರ್ಹರಾಗಿರುವುದಿಲ್ಲ.

ಈ ಪರೀಕ್ಷೆಗಳಿಗೆ ಒಳಗಾಗುವುದರಲ್ಲಿ ಅಪಾಯಗಳಿವೆಯೇ?

ಈ ಎಲ್ಲಾ ಪರೀಕ್ಷೆಗಳು ಆಕ್ರಮಣಶೀಲವಲ್ಲದ, ಸಂಪೂರ್ಣವಾಗಿ ಸುರಕ್ಷಿತವಾಗಿದೆ ಮತ್ತು ಹೇಗಾದರೂ ನಿಮಗೆ ಹಾನಿ ಅಥವಾ ಕಿರಿಕಿರಿಯನ್ನುಂಟು ಮಾಡುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಯಾವುದೇ ಅಪಾಯಗಳು ಅಥವಾ ಯಾವುದೇ ಅನಾನುಕೂಲತೆಗಳಿಲ್ಲ. ನಮ್ಮ ಅಧ್ಯಯನವು ಆಕ್ರಮಣಕಾರಿಯಲ್ಲದ ಕಾರಣ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ನಿಮಗೆ ಯಾವುದೇ ಅಪಾಯವನ್ನುಂಟು ಮಾಡುವುದಿಲ್ಲ ಆದರೆ ನಿಮ್ಮ ಹಿಗ್ಗಿಸುವ ಸಾಮರ್ಥ್ಯವನ್ನು ಮೀರಿ ನೀವು ಮಾಡಿದರೆ ಅದು ಉಳುಕು ಮತ್ತು ನೋವಿನಲ್ಲಿ ಕೊನೆಗೊಳ್ಳಬಹುದು. ಹಾಗಿದ್ದಲ್ಲಿ ನೀವು ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಯನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು, ಇದರಿಂದಾಗಿ ನಿಮಗೆ ಸರಿಯಾದ ಸಮಯದಲ್ಲಿ ಅಗತ್ಯವಾದ ಆರೈಕೆ / ಚಿಕಿತ್ಸೆಯನ್ನು ನೀಡಲಾಗುವುದು.

ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ವೆಚ್ಚ

ಅಧ್ಯಯನದ ಅವಧಿಯಲ್ಲಿ ಹಸ್ತಕ್ಷೇಪಕ್ಕಾಗಿ ಅಥವಾ ಪ್ರಯೋಗಾಲಯ ಪರೀಕ್ಷೆಗೆ ಪಾವತಿಸಲು ನಿಮಗೆ ಅರ್ಹತೆ ಇರುವುದಿಲ್ಲ. ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದ್ದಕ್ಕಾಗಿ ನಿಮಗೆ ಹಣ ನೀಡಲಾಗುವುದಿಲ್ಲ.

ಮಾಹಿತಿಯ ಗೌಪ್ಯತೆ

ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಅನನ್ಯ ಗುರುತಿನ ಸಂಖ್ಯೆಗಳನ್ನು ಬಳಸಿಕೊಂಡು ಕೋಡ್ ಮಾಡಲಾಗುತ್ತದೆ, ಅದು ತನಿಖಾ ತಂಡಕ್ಕೆ ಮಾತ್ರ ತಿಳಿಯುತ್ತದೆ. ಈ ಕೋಡ್ ಅನ್ನು ಮಾತ್ರ ಎಲ್ಲಾ ಮೌಲ್ಯಮಾಪನ ಹಾಳೆಗಳಲ್ಲಿ ಸೂಚಿಸಲಾಗುತ್ತದೆ, ಆದ್ದರಿಂದ ನಿಮ್ಮ ಗುರುತನ್ನು ಯಾರಿಗೂ ಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲ. ನಿಮ್ಮ ಹೆಸರನ್ನು ಆಸ್ಪತ್ರೆಯ ಹೊರಗೆ ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ ಅಥವಾ ಅಧ್ಯಯನದ ಪರಿಣಾಮವಾಗಿ ಯಾವುದೇ ವರದಿಗಳು ಅಥವಾ ಪ್ರಕಟಣೆಗಳಲ್ಲಿ ಕಾಣಿಸುವುದಿಲ್ಲ. ಈ ಸಂಶೋಧನೆಯಿಂದ ಉತ್ಪತ್ತಿಯಾಗುವ

ದತ್ತಾಂಶವು ಅನಾಮಧೇಯವಾಗಿರುತ್ತದೆ, ಇದರಲ್ಲಿ ವ್ಯಕ್ತಿಗಳ ಗುರುತಿನ ಸೂಚನೆಯಿಲ್ಲ. ಆದಾಗ್ಯೂ, ನಡೆಸಿದ ಪರೀಕ್ಷೆಗಳ ಫಲಿತಾಂಶಗಳು ನಿಮಗೆ ಬಹಿರಂಗವಾಗುತ್ತವೆ ಮತ್ತು ನಿಮಗೆ ವಿವರಿಸಲ್ಪಡುತ್ತವೆ. ಫಲಿತಾಂಶಗಳ ನಕಲನ್ನು ಸಹ ನಿಮಗೆ ನೀಡಲಾಗುವುದು.

ನೀವು ನೀಡಿದ ಮಾದರಿಗಳಿಗೆ (ಡೇಟಾ) ಏನಾಗುತ್ತದೆ?

ಪಡೆದ ಡೇಟಾವನ್ನು ವೈಜ್ಞಾನಿಕವಾಗಿ ವಿಶ್ಲೇಷಿಸಲಾಗುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಫಲಿತಾಂಶಗಳನ್ನು ವೈಜ್ಞಾನಿಕ ನಿಯತಕಾಲಿಕಗಳಲ್ಲಿ ಪ್ರಕಟಿಸಬಹುದು. ಫಲಿತಾಂಶಗಳನ್ನು ವೈಜ್ಞಾನಿಕ ಸಮ್ಮೇಳನಗಳು / ಸೆಮಿನಾರ್‌ಗಳಲ್ಲಿ ಸಹ ಪ್ರಸ್ತುತಪಡಿಸಬಹುದು. ನಮ್ಮ ಸಂಶೋಧನೆಯಿಂದ ಇತರ ಆಸಕ್ತರು ಕಲಿಯಬಹುದಾದ ಸಲುವಾಗಿ ನಾವು ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸುತ್ತೇವೆ.

ಅಧ್ಯಯನವನ್ನು ಯಾರು ಆಯೋಜಿಸುತ್ತಿದ್ದಾರೆ?

ಡಾ.ನೀತಿನಕುಮಾರ್ ಪಾಟೀಲ್ ಅವರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ಇಂಟಿಗ್ರೇಟಿವ್ ಮೆಡಿಸಿನ್ ವಿಭಾಗದ ಪಿಎಚ್‌ಡಿ ಸಂಶೋಧನಾ ವಿದ್ಯಾರ್ಥಿ ಯಾದ ಶ್ರೀ ಶ್ರೀನಿವಾಸ್ ಎಂ ಈ ಸಂಶೋಧನೆಯನ್ನು ನಡೆಸುತ್ತಿದ್ದಾರೆ. ಕೋಲಾರದ ತಮಾಕಾದ ಶ್ರೀ ದೇವರಾಜ್ ಉರ್ಸ್ ಅಕಾಡೆಮಿ ಆಫ್ ಹೈಯರ್ ಎಜುಕೇಶನ್ ಅಂಡ್ ರಿಸರ್ಚ್‌ನಲ್ಲಿ ಇಂಟಿಗ್ರೇಟಿವ್ ಮೆಡಿಸಿನ್ ವಿಭಾಗದ ಪ್ರಾಧ್ಯಾಪಕರು. ಮತ್ತು ನಮ್ಮ ಸಹ-ಮಾರ್ಗದರ್ಶಿ ಡಾ.ಜಗ್ಮೋಹನ್ ಎಸ್ ವಿ, ಸಹಾಯಕ. ಪ್ರೊಫೆಸರ್. , ತಮಕಾದ ಆರ್.ಎಲ್.ಜಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರದಲ್ಲಿ ಶ್ವಾಸಕೋಶಶಾಸ್ತ್ರ ವಿಭಾಗ

ಈ ಅಧ್ಯಯನವನ್ನು ಯಾರು ಪರಿಶೀಲಿಸಿದ್ದಾರೆ?

ಶ್ರೀ ದೇವರಾಜ್ ಉರ್ಸ್ ಅಕಾಡೆಮಿ ಆ ಹೈಯರ್ ಎಜುಕೇಶನ್ ಅಂಡ್ ರಿಸರ್ಚ್ ನ ಪಿಎಚ್‌ಡಿ ಡಾಕ್ಟರೇಟ್ ಸಮಿತಿ ಅದರ ವೈಜ್ಞಾನಿಕ ವಿಷಯದ ಪ್ರಸ್ತಾಪವನ್ನು ಪರಿಶೀಲನೆ ಮಾಡಲಾಗಿದೆ; ಈ ಅಧ್ಯಯನವನ್ನು ನೈತಿಕ ಅಂಶಗಳು / ಮಾನದಂಡಗಳಿಗಾಗಿ ಕೇಂದ್ರ ನೈತಿಕ ಸಮಿತಿ, ಶ್ರೀ ದೇವರಾಜ್ ಉರ್ಸ್ ಅಕಾಡೆಮಿ ಆಫ್ ಹೈಯರ್ ಎಜುಕೇಶನ್ ಅಂಡ್ ರಿಸರ್ಚ್ ಅನುಮೋದಿಸಿದೆ.

ಈ ಅಧ್ಯಯನದ ಕುರಿತು ನಿಮಗೆ ಹೆಚ್ಚಿನ ಮಾಹಿತಿ ಬೇಕಾದರೆ, ದಯವಿಟ್ಟು ಅಧ್ಯಯನದ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ನೀವು ಈ ಕೆಳಗಿನವುಗಳನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಶ್ರೀ ಶ್ರೀನಿವಾಸ್ ಎಂ

ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: 9880286653 / 8310799813

ಇಮೇಲ್: srinivasphd2020@gmail.com

ಡಾ.ನೀತಿನಕುಮಾರ್ ಪಾಟೀಲ್

ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: 9886211008

ಇಮೇಲ್: ayushnitin@gmail.com

ಡಾ ಜಗಮೋಹನ್ ಎಸ್ ವಿ

ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: 9449203539

ಇಮೇಲ್: drjagmohan99@gmail.com

ಈ ಮಾಹಿತಿಯನ್ನು ಓದಲು ಸಮಯ ತೆಗೆದುಕೊಂಡಿದ್ದಕ್ಕಾಗಿ ಧನ್ಯವಾದಗಳು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದನ್ನು ಪರಿಗಣಿಸಲು ನೀವು ನಿರ್ಧರಿಸಿದರೆ, ನಿಮ್ಮ ಮಾಹಿತಿಗಾಗಿ ಈ ಕರಪತ್ರದ ನಕಲನ್ನು ನಿಮಗೆ ನೀಡಲಾಗುವುದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಯಾವುದೇ ಹೆಚ್ಚುವರಿ ವೆಚ್ಚಗಳಿಲ್ಲ ಎಂದು ನೀವು ಗಮನಿಸಬಹುದು.

APPENDIX II-C

INFORMED CONSENT FORM

Name of the study - "Effect of Integrated Yoga as an adjuvant therapy to standard care in Pulmonary Tuberculosis- A Randomized Control Trail".

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant_____ Hospital IP/OP number:_____

Signature of Participant _____ Date _____

For illiterate -

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness_____ AND Thumb print of participant

Signature of witness _____ Date _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant with the best of my ability. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher taking the consent_____

Signature of Researcher taking the consent_____ Date_____

PRINCIPAL INVESTIGATOR'S NAME: Mr Srinivas M

MOBILE NUMBER: 9880286653 **Email ID:** srinivasphd2020@gmail.com

Dr Neetinakumar Patil

Mobile No: 9886211008 **Email:** ayushnitin@gmail.com

Dr Jagmohan S V

Mobile No: 9449203539 **Email:** drjagmohan99@gmail.com

APPENDIX II-C

INFORMED CONSENT FORM-III (KANNADA)

ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ಪತ್ರ:

ಅಧ್ಯಯನದ ಹೆಸರು - "ಪಲ್ಮನರಿ ಕ್ಷಯರೋಗದಲ್ಲಿ ಗುಣಮಟ್ಟದ ಆರೈಕೆಗೆ ಸಹಾಯಕ ಚಿಕಿತ್ಸೆಯಾಗಿ ಸಂಯೋಜಿತ ಯೋಗದ ಪರಿಣಾಮ- ಯಾದೃಚ್ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗ ".

ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಪಟ್ಟ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಓದಿದ್ದೇನೆ ಅಥವಾ ಅದನ್ನು ನನಗೆ ಓದಲಾಗಿದೆ. ಅದರ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುವ ಮುಕ್ತ ಅವಕಾಶ ನನಗೆ ಇತ್ತು ಮತ್ತು ನಾನು ಕೇಳಿದ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ನನಗೆ ತೃಪ್ತಿಕರವಾದ ಉತ್ತರಸಿಕ್ಕಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪಿದ್ದೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು _____
ಭಾಗವಹಿಸುವವರ ಸಹಿ _____ **ದಿನಾಂಕ** _____

ಅನಕ್ಷರಸ್ಥರಿಗೆ -
ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಬಹುದಾದ ಇವರಿಗೆ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಎಲ್ಲಾ ವಿಷಯಗಳನ್ನು ತಿಳಿಸಿ ಹೇಳಲಾಗಿದೆ ಮತ್ತು ಇದಕ್ಕೆ ನಾನು ಸಾಕ್ಷಿಯಾಗಿದ್ದೇನೆ. ಈ ವ್ಯಕ್ತಿಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಮುಕ್ತ ಅವಕಾಶ ಇದ್ದು ಆತ ಕೇಳಿದ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ಸಂಶೋಧಕರು ಸಮರ್ಪಕವಾದ ಉತ್ತರ ನೀಡಿದ್ದಾರೆ. ಇದರನಂತರ, ಈ ವ್ಯಕ್ತಿಯು ತನ್ನ ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಒಪ್ಪಿಗೆ ನೀಡಿದ್ದಾನೆ ಎಂದು ನಾನು ಖಚಿತಪಡಿಸುತ್ತೇನೆ.

ಸಾಕ್ಷಿಯ ಹೆಸರು _____ ಮತ್ತು **ಭಾಗವಹಿಸುವವರ ಹೆಬ್ಬೆರಳು ಮುದ್ರಣ**
ಸಾಕ್ಷಿಯ ಸಹಿ _____ **ದಿನಾಂಕ** _____

ಒಪ್ಪಿಗೆ ಪಡೆಯುವ ಸಂಶೋಧಕ / ವ್ಯಕ್ತಿಯ ಹೇಳಿಕೆ.
ನನಗೆ ತಿಳಿದ ಮಟ್ಟಿಗೆ ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಸಂಪೂರ್ಣ ಮಾಹಿತಿಯನ್ನು ಈ ವ್ಯಕ್ತಿಗೆ ಓದಿ ಹೇಳಿದ್ದೇನೆ. ಆತ ಕೇಳಿದ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳಿಗೆ ಸಮರ್ಪಕವಾಗಿ ಉತ್ತರ ನೀಡಿದ್ದೇನೆಂದು ನಾನು ಖಚಿತಪಡಿಸುತ್ತೇನೆ. ಒಪ್ಪಿಗೆ ನೀಡುವಂತೆ ಈ ವ್ಯಕ್ತಿಗೆ ಯಾವುದೇ ರೀತಿಯಿಂದ ಒತ್ತಾಯಿಸಲಾಗಿಲ್ಲ. ಈ ವ್ಯಕ್ತಿಯು ತನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ನೀಡಿದ್ದಾರೆ ಎಂದು ನನಗೆ ಖಚಿತವಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವ ಈ ವ್ಯಕ್ತಿಗೆ ತಿಳುವಳಿಕೆಯಿಂದ ನೀಡಿದ ಸಮ್ಮತಿ ಪತ್ರದ ಒಂದು ಪ್ರತಿಯನ್ನು ನೀಡಿದ್ದೇನೆ.
ಒಪ್ಪಿಗೆ ತೆಗೆದುಕೊಳ್ಳುವ ಸಂಶೋಧಕರ ಹೆಸರು _____
ಒಪ್ಪಿಗೆಯನ್ನು ತೆಗೆದುಕೊಳ್ಳುವ ಸಂಶೋಧಕರ ಸಹಿ _____
ದಿನಾಂಕ _____

ಮುಖ್ಯ ಸಂಶೋಧಕರು : ಶ್ರೀ ಶ್ರೀನಿವಾಸ್ ಎಂ **ಮೊಬೈಲ್ ಸಂಖ್ಯೆ:** 9880286653
ಇಮೇಲ್ ID: srinivasphd2020@gmail.com
ಡಾ.ನೀತಿನಕುಮಾರ್ ಪಾಟೀಲ್ ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: 9886211008 ಇಮೇಲ್: ayushnitin@gmail.com
ಡಾ ಜಗಮೋಹನ್ ಎಸ್ ವಿ ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: 9449203539 ಇಮೇಲ್: drjagmohan99@gmail.com

APPENDIX III-A

Hamilton Depression Rating Scale (HDRS)

PLEASE COMPLETE THE SCALE BASED ON A STRUCTURED INTERVIEW

Instructions: for each item select the one "cue" which best characterizes the patient. Be sure to record the answers in the appropriate spaces (positions 0 through 4).

1 DEPRESSED MOOD *(sadness, hopeless, helpless, worthless)*

0 |__| Absent.

1 |__| These feeling states indicated only on questioning.

2 |__| These feeling states spontaneously reported verbally.

3 |__| Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep.

4 |__| Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication.

2 FEELINGS OF GUILT

0 |__| Absent.

1 |__| Self reproach, feels he/she has let people down.

2 |__| Ideas of guilt or rumination over past errors or sinful deeds.

3 |__| Present illness is a punishment. Delusions of guilt.

4 |__| Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

3 SUICIDE

0 |__| Absent.

1 |__| Feels life is not worth living.

2 |__| Wishes he/she were dead or any thoughts of possible death to self.

3 |__| Ideas or gestures of suicide.

4 |__| Attempts at suicide (any serious attempt rate 4).

4 INSOMNIA: EARLY IN THE NIGHT

0 |__| No difficulty falling asleep.

1 |__| Complains of occasional difficulty falling asleep, i.e. more than 1⁄2 hour.

2 |__| Complains of nightly difficulty falling asleep.

5 INSOMNIA: MIDDLE OF THE NIGHT

0 |__| No difficulty.

1 |__| Patient complains of being restless and disturbed during the night.

2 |__| Waking during the night – any getting out of bed rates 2 (except for purposes of voiding).

6 INSOMNIA: EARLY HOURS OF THE MORNING

0 |__| No difficulty.

1 |__| Waking in early hours of the morning but goes back to sleep.

2 |__| Unable to fall asleep again if he/she gets out of bed.

7 WORK AND ACTIVITIES

0 |__| No difficulty.

1 |__| Thoughts and feelings of incapacity, fatigue or weakness related to activities, work or hobbies.

2 |__| Loss of interest in activity, hobbies or work – either directly reported by the patient or indirect in listlessness, indecision and vacillation (feels he/she has to push self to work or activities).

3 |__| Decrease in actual time spent in activities or decrease in productivity. Rate 3 if the patient does not spend at least three hours a day in activities (job or hobbies) excluding routine chores.

4 |__| Stopped working because of present illness. Rate 4 if patient engages in no activities except routine chores, or if patient fails to perform routine chores unassisted.

8 RETARDATION (slowness of thought and speech, impaired ability to concentrate, decreased motor activity)

0 |__| Normal speech and thought.

1 |__| Slight retardation during the interview.

2 |__| Obvious retardation during the interview.

3 |__| Interview difficult.

4 |__| Complete stupor.

9 AGITATION

0 |__| None.

1 |__| Fidgetiness.

2 |__| Playing with hands, hair, etc.

3 |__| Moving about, can’t sit still.

4 |__| Hand wringing, nail biting, hair-pulling, biting of lips.

10 ANXIETY PSYCHIC

0 |__| No difficulty.

1 |__| Subjective tension and irritability.

2 |__| Worrying about minor matters.

3 |__| Apprehensive attitude apparent in face or speech.

4 |__| Fears expressed without questioning.

11 ANXIETY SOMATIC (physiological concomitants of anxiety) such as:

gastro-intestinal – dry mouth, wind, indigestion, diarrhea, cramps, belching cardio-vascular – palpitations, headaches respiratory – hyperventilation, sighing urinary frequency sweating

0 |__| Absent.

1 |__| Mild.

2 |__| Moderate.

3 |__| Severe.

4 |__| Incapacitating.

12 SOMATIC SYMPTOMS GASTRO-INTESTINAL

0 |__| None.

1 |__| Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen.

2 |__| Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for gastro-intestinal symptoms.

13 GENERAL SOMATIC SYMPTOMS

0 |__| None.

1 |__| Heaviness in limbs, back or head. Backaches, headaches, muscle aches. Loss of energy and fatigability.

2 |__| Any clear-cut symptom rates 2.

14 GENITAL SYMPTOMS (symptoms such as loss of libido, menstrual disturbances)

0 |__| Absent.

1 |__| Mild.

2 |__| Severe.

15 HYPOCHONDRIASIS

0 |__| Not present.

1 |__| Self-absorption (bodily).

2 |__| Preoccupation with health.

3 |__| Frequent complaints, requests for help, etc.

4 |__| Hypochondriacal delusions.

16 LOSS OF WEIGHT *(RATE EITHER a OR b)*

a) According to the b) According to weekly patient: measurements:

0 |__| No weight loss. 0 |__| Less than 1 lb weight loss in week.

1 |__| Probable weight 1 |__| Greater than 1 lb weight loss loss associated with in week. present illness.

2 |__| Definite (according 2 |__| Greater than 2 lb weight loss to patient) weight in week.

loss.

3 |__| Not assessed. 3 |__| Not assessed.

17 INSIGHT

0 |__| Acknowledges being depressed and ill.

1 |__| Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for

rest,

2 |__| Denies being ill at all.

Total score: |__|__|

This scale is in the public domain.
The range of score for HDRS as follows,

- 0-7_____These considered as normal
- 8-16_____ Mild depression
- 17-23_____ Moderate depression
- Over 24_____ Severe depression
- The maximum score being 52 on the 17-point scale.

APPENDIX III-B

WHOQOL-BREF QUESTIONNAIRE

1. **The following questions ask how you feel about your quality of life, health, or other areas of your life.**
2. **Please choose the answer that appears most appropriate.**
3. **If you are unsure about which response to give to a question, the first response you think of is often the best one.**
4. **Please indicate your answer by marking the symbol √ in the box; like this** √

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

Sl.no	Particulars	Very poor	Poor	Neither poor nor good	Good	Very good
1	How would you rate your quality of life?					

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2	How satisfied are you with your health?					

The following questions ask about **how much** you have experienced certain things in the **last four weeks**.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3	To what extent do you feel that physical pain prevents you from doing what you need to do?					
4	How much do you need any medical treatment to function in your daily life?					
5	How much do you enjoy life?					
6	To what extent do you feel your life to be meaningful?					

		Not at all	A little	A moderate amount	Very much	Extremely
7	How well are you able to concentrate?					
8	How safe do you feel in your daily life?					
9	How healthy is your physical environment?					

Continued….

The following questions ask about **how completely** you experience or were able to do certain things in the **last four weeks**.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?					
11.	Are you able to accept your bodily appearance?					
12.	Have you enough money to meet your needs?					
13.	How available to you is the information that you need in your day-to-day life?					
14.	To what extent do you have the opportunity for leisure activities?					

		Very poor	Poor	Neither poor nor good	Good	Very good
15	How well are you able to get around?					

		Very dissatisfied	Dissatisfied	Neither satisfied nor Dissatisfied	Satisfied	Very satisfied
16	How satisfied are you with your sleep?					
17	How satisfied are you with your ability to perform your daily living activities?					
18	How satisfied are you with your capacity for work?					
19	How satisfied are you with yourself?					
20	How satisfied are you with your personal relationships?					
21	How satisfied are you with your sex life?					
22	How satisfied are you with the support you get from your friends?					
23	How satisfied are you with the conditions of your living place?					
24	How satisfied are you with your access to health services?					
25	How satisfied are you with your transport?					

The following question refers to **how often** you have felt or experienced certain things in the **last four weeks.**

		Never	Seldom	Quite often	Very Often	Always
26	How often do you have negative feelings such as blue mood, despair, anxiety, depression?					

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APPENDIX-IV

Institutional Ethical Clearence Certificate

Sri Devaraj Urs Academy of Higher Education & Research
(Deemed to be University
Post Box 62, Tamaka, Kolar 563103, Karnataka

Institutional Ethics Committee
Faculty of Allied Health & Basic Sciences

Dr M Jayaram
Member Secretary

Ref: SDUAHER/ IEC/ MJ/ 13 / 22-23 7 October 2022

Mr M. Srinivas
Ph.D Scholar,
Department of Integrative Medicine
SDUAHER, Tamaka, Kolar ..... Through his Guide

Ethical Approval from IEC-FAH&BS

1)	Name of the investigator	Mr M Srinivas
2)	Reference number of the investigator	20PY7003 His application Ref; SDUAHER/KLR/ IM/ 105/ 2022-23, dated 29 July 22 His modified proposal dated 4 September 2022
3)	Title of the research proposal	Effect of integrated Yoga as an adjuvant therapy to standard care in pulmonary tuberculosis - A randomized control trial
4)	Name of the Guide Co-guide	Dr Neetinakumar Patil Dr SV Jagmohan
5)	Nature of the research proposal	Ph.D work
6)	New review / Revised review	Revised review
7)	Date of the Ethics Committee meeting	13 August 2022 Modified proposal reviewed through circulation as per earlier decision Chairman's approval on 29 September 2022
8)	Date(s) of previous review(s), if revised	13 August 2022
9)	Comments:	Nil

Phone: 08152-243240 Mobile: 9449264716 email: spa@sduaher.ac.in drmjay16@gmail.com Web: sduaher.ac.in

10) **Decision of the IEC:**

a) **The Ethics committee approves the research proposal and the study related documents for its ethical aspects.**

b) The investigator must file a 1-page report on the status of the study, especially on issues that are of ethical importance, to the Ethics committee every year

c) The investigator must file a 1-page final report to the Ethics committee within 6 months from the completion of the study.

d) The Ethics committee draws the attention of the researcher to the undertaking he/she has given. The investigator must report any change in the study protocol / details to the Ethics committee and seek fresh ethical approval, if indicated.

11. The Ethics committee hereby gives approval for all publications as well as for all presentations at conferences, symposia, seminars etc. that are the outcome of this project subject to the investigator fulfilling the assurances given to the participants of the study (as in the participant information sheet and informed consent form)

12. The Ethics Committee reserves the right to visit the project site, access the project-related papers, and verify the implementation of ethical practices in the project. The investigator(s) shall cooperate with the Ethical committee or its representatives in this regard. Failure to cooperate may result in withdrawal of the Ethical approval.

13. Members who approved the modified proposal through circulation::

a) Prof. B. S. Shankaranarayan — Chairperson
Professor of Neurophysiology and Registrar
NIMHANS, Bangalore -560029

b) Dr. S N Anand — Member
Senior Manager - CBR, Mobility India.
Bangalore –560056

c) Dr. B G Prakash — Member
Dean, College of Horticulture,
GKVK Campus, Bangalore

d) Mrs Lakshmi Bhatt — Member
Lecturer, RL Jalappa Central School
Kolar, Tamaka 563101

e) Dr. C D Dayanand — Member
Professor and Head, Department of AHS,
and Dean - FAH&BS, SDUAHER,
Tamaka, Kolar – 563101

f) Dr. Azeem Mohiuddin — Member
Professor of Otolaryngology,

and Director, Research and Development
SDUAHER, Tamaka, Kolar – 563101

g) Dr. M Madhavi Reddy — Member
Professor and Head, Department of Clinical Nutrition
SDUAHER, Tamaka, Kolar – 563101

h) Dr. M Jayaram — Member Secretary
Professor, Speech Pathology & Audiology
SDUAHER, Tamaka, Kolar – 563101

Dr M Jayaram
Member Secretary

Prof B S Shanakaranarayana Rao
Chairperson

Copy to:

a) PA to Vice Chancellor, SDUAHER
b) Dean, Faculty of Allied Health & Basic Sciences
c) Ph.D Coordinator, SDUAHER
d) Registrar, SDUAHER
e) Director, Research and Development
f) Dr Neetinakumar Patil, Guide
g) Head, Department of Integrative Medicine

APPENDIX-V

District Health Officer (DHO) Permission Letter

ಕರ್ನಾಟಕ ಸರ್ಕಾರ

ಜಿಲ್ಲಾ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣಾಧಿಕಾರಿಗಳ ಕಛೇರಿ

ಕೆ.ಎನ್. ಸ್ಯಾನಿಟೋರಿಯಂ ಆವರಣ, ಬಂಗಾರಪೇಟೆ ರಸ್ತೆ, ಕೋಲಾರ – 563102

ಸಂಖ್ಯೆ:ಡಿಟಿಸಿಕೆ/53/2022–23 ದಿನಾಂಕ: 19–12–2022

ಅಧಿಕೃತ ಜ್ಞಾಪನಾ ಪತ್ರ

ವಿಷಯ: ಎಸ್.ಟಿ.ಇ.ಪಿ ಕಾರ್ಯಕ್ರಮದ ಅಧ್ಯಯನ ನಡೆಸಲು ಮೆಡಿಕಲ್ ಕಾಲೇಜಿನಿಂದ ಆಗಮಿಸುವ ತಂಡಗಳಿಗೆ ಸಹಕಾರ ನೀಡುವ ಕುರಿತು.

ಉಲ್ಲೇಖ: (1) ಶ್ರೀ.ಶ್ರೀನಿವಾಸ.ಎಂ, PHd Scholar ಎಸ್.ಡಿ.ಯು.ಎಂ.ಸಿ.. ಕೋಲಾರ ರವರ ಮನವಿ ಪತ್ರದ ದಿನಾಂಕ 08–12–2022

(2) ಡಾ॥ಸಮುದ್ಯಾತ, ಸಹ ಪ್ರಾದ್ಯಾಪಕರು, ಎಸ್.ಡಿ.ಯು.ಎಂ.ಸಿ. ಕೋಲಾರ ರವರ ಪತ್ರ ಸಂಖ್ಯೆ: SDUMC/KLR/COMM/767/2022-23 ದಿನಾಂಕ 12–12–2022

* * * * *

ಮೇಲ್ಕಂಡ ವಿಷಯಕ್ಕೆ ಸಂಬಂದಿಸಿದಂತೆ ಉಲೇಖಿತ ಪತ್ರಗಳನ್ವಯ ಶ್ರೀ.ದೇವರಾಜು ಅರಸು ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯ, ಟಮಕ, ಕೋಲಾರ ವತಿಯಿಂದ ಕ್ಷಯರೋಗದ ಕುರಿತಾಗಿ ಸಂಶೋಧನ ಅಧ್ಯಯನ ನಡೆಸಲು ವೈದ್ಯಾಧಿಕಾರಿಗಳು ಹಾಗೂ ಸಿಬ್ಬಂದಿ ಯೋಜನೆಯನ್ನು ಹಮ್ಮಿಕೊಂಡಿರುತ್ತಾರೆ. ಎಸ್.ಟಿ.ಇ.ಪಿ ಅಡಿಯಲ್ಲಿ ಸಿಬ್ಬಂದಿಗಳ, ನಿಕ್ಷಯ ಪೋರ್ಟಲ್ ಕುರಿತಾಗಿ ಮತ್ತು ಚಿಕಿತ್ಸೆಯಲ್ಲಿರುವ ಕ್ಷಯರೋಗಿಗಳೊಂದಿಗೆ ಪರಸ್ಪರ ಚರ್ಚಿಸಲು ಹಾಗೂ ಶ್ವಾಸಕೋಶದ ಕ್ಷಯರೋಗಿಗಳಿಗೆ ಯೋಗದ ಮಧ್ಯಸ್ಥಿಕೆಯನ್ನು ಒದಗಿಸಲು ಎಸ್.ಡಿ.ಯು.ಎಂ.ಸಿ. ತಂಡ ಚಿಕಿತ್ಸಾ ಘಟಕಗಳಿಗೆ ಹಾಗೂ ಆರೋಗ್ಯ ಮತ್ತು ಕ್ಷೇಮ ಕೇಂದ್ರಗಳಿಗೆ ಬೇಟಿ ನೀಡಲಿರುವುದಾಗಿ ಈ ಕಛೇರಿಗೆ ಪತ್ರ ಸಲ್ಲಿಸಿರುತ್ತಾರೆ. ಆದ್ದರಿಂದ ಮೆಡಿಕಲ್ ಕಾಲೇಜಿನಿಂದ ಆಗಮಿಸುವ ತಂಡದವರಿಗೆ ಸಹಕಾರ ನೀಡಲು ಈ ಮೂಲಕ ಸೂಚಿಸಿದೆ.

ಜಿಲ್ಲಾ ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ
ಕಲ್ಯಾಣಾಧಿಕಾರಿಗಳು, ಕೋಲಾರ

ಪ್ರತಿಯನ್ನು:

1. ಜಿಲ್ಲಾ ಸರ್ವೇಕ್ಷಣಾಧಿಕಾರಿಗಳು, ಜಿಲ್ಲಾ ಸಾಂಕ್ರಾಮಿಕ ರೋಗಗಳ ಕಣ್ಗಾವಲು ಘಟಕ, ಕೋಲಾರ ರವರ ಮಾಹಿತಿಗೆ ನೀಡಿದೆ.
2. ಜಿಲ್ಲಾ ಕ್ಷಯರೋಗ ನಿವಾರಣಾಧಿಕಾರಿಗಳು, ಕೋಲಾರ ರವರ ಮಾಹಿತಿಗೆ ನೀಡಿದೆ.
3. ಎಲ್ಲಾ ತಾಲ್ಲೂಕು ಆರೋಗ್ಯಾಧಿಕಾರಿಗಳು, ಕೋಲಾರ ಜಿಲ್ಲೆ ರವರ ಮಾಹಿತಿಗೆ ನೀಡಿದೆ.
4. ಎಲ್ಲಾ ಆಡಳಿತ ವೈದ್ಯಾಧಿಕಾರಿಗಳು / ವೈದ್ಯಾಧಿಕಾರಿಗಳು, ಸಾ.ಆ/ಪ್ರಾ.ಆ.ಕೇ/ಸ.ಆ.ಕೇ/ನ.ಪ್ರಾ.ಅ.ಕೇ, ಕೋಲಾರ ಜಿಲ್ಲೆ ರವರ ಮಾಹಿತಿಗೆ ನೀಡಿದೆ.
5. ಎಲ್ಲಾ ಸಮುದಾಯ ಆರೋಗ್ಯ ಅಧಿಕಾರಿಗಳು, ಕೋಲಾರ ಜಿಲ್ಲೆ ರವರ ಮಾಹಿತಿ ಮತ್ತು ಕ್ರಮಕ್ಕೆ ನೀಡಿದೆ.
6. ಎಲ್ಲಾ ಎಸ್.ಟಿ.ಇ.ಪಿ ಸಿಬ್ಬಂದಿಗಳ ಮಾಹಿತಿ ಮತ್ತು ಕ್ರಮಕ್ಕೆ ನೀಡಿದೆ.
7. ಕಛೇರಿ ಪ್ರತಿ

APPENDIX VI

DOCTORAL RESEARCH ADVOSRY COMMITTEE (DRAC)

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH
TAMAKA, KOLAR-563 103 KARNATAKA, INDIA
Centre for Ph.D. Programs

No. SDUAHER/KLR/CMP/ 325 /2020-21 Date: 04-11-2020

PROCEEDINGS OF THE DOCTORAL COMMITTEE MEETING

A meeting of the Doctoral Advisory Committee constituted for the purpose of review the Ph.D. Research Proposal/Preliminary Synopsis submitted by Ph.D. Scholar (January Session 2020) was held on 12.10.2020 on Virtual Zoom Platform under the Chairmanship of Dr. G. Pradeep Kumar, Vice-Chancellor of Sri Devaraj Urs Academy of Higher Education and Research.

Members present

Dr. Madhavi Reddy	-	Dean FAHBS (I/C)
Dr. N.Sarala	-	Director of Academics
Dr. Nitin Patil. J	-	HoD, of Integrative Medicine and Supervisor
Dr. Hemanth Bhargav	-	Asst. Prof. NIMHANS, Bangalore
Dr .C.D.Dayanand	-	Member Secretary

The member secretary introduced the external member to the committee with permission of the chair and allowed Ph.D. student **Mr. Srinivasa. M** to present the Ph.D. Research Proposal title as "***Effective of Integrated Yoga as an adjuvant therapy to standard care in Pulmonary Tuberculosis-A Randomized Control Trail".***

The Doctoral Advisory Committee evaluated the scientific content of research proposal & suggested the followings.

- Should take care of COVID-19 precautions while doing PFT
- Adding Hamilton Depression Rating Scale (HDRA) questionnaire instead of Beck's questionnaire for depression.
- Randomization: Random allocation by concealment-using opaque envelope.
- In exclusion criteria-Adding Extra pulmonary tuberculosis
- Yoga module has to be validated before the intervention.
- Feasibility study can be conducted for 10-15 TB patients
- Exploring the feasibility of incorporating Bastrika in Yoga module
- Statistical analysis: RM-ANOVA looks more suitable
- Exploring the possibility of adding the chest X-ray, weight change and sputum results.
- Follow up once study completes-should follow up for year to see the aftermath effects.
- In inclusion and exclusion criterion specify about whether micor biologically and clinically diagnosed pulmonary tuberculosis patients.
- Due to COVID-19 how to take care of doing PFT test.
- Obtain central ethics committee approval before commencement of study.

Ph. D Scholar advised to incorporate above suggestions in Research proposal and submit the revised Research proposal.

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APPENDIX-VII

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Effect of Integrated Yoga as an adjuvant therapy to standard care in Pulmonary Tuberculosis- A Randomized Control Trial

Chapter-1: Introduction

Background

Tuberculosis (TB) is the most contagious and most common infectious disease in the world. (1) Tuberculosis has been a significant public health concern for centuries, with evidence of the disease dating back to ancient civilizations. Mycobacterium tuberculosis (MTB) bacteria causes tuberculosis. MTB has ancient origins of living for 70,000 years of history. It was historically called consumption disease due to weight loss. (2) However, modern scientific understanding and research on TB have advanced considerably.

In the late 19th and early 20th centuries, the discovery of the tubercle bacillus by Robert Koch in 1882 significant crucial turning point in TB research. (2) This breakthrough laid the foundation for understanding the microbial cause of the disease, enabling considerable progress in diagnosis, treatment, and prevention. Throughout the 20th century, TB research focused on developing effective treatments, particularly with the discovery and widespread use of antibiotics such as streptomycin, isoniazid, rifampicin, and ethambutol. (3,4) These drugs revolutionized TB therapy, leading to significant reductions in mortality and transmission rates.

However, the emergence of drug-resistant strains, particularly multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), presented new challenges and spurred renewed research efforts. (5) Scientists have been investigating new treatment regimens, diagnostic techniques, and vaccines to combat these resistant strains and improve TB control efforts.

In recent years, research has also focused on addressing TB in specific populations, such as those co-infected with HIV/AIDS, as well as improving TB surveillance and control strategies globally. Additionally, there has been a growing emphasis on understanding the socio-economic factors contributing to TB transmission and implementing interventions to address them effectively. (6,7) Advancements in molecular biology, genomics, and computational modeling have further enhanced our understanding of TB pathogenesis, drug resistance mechanisms, and host-pathogen interactions. These advances offer promising avenues for the development of novel interventions and strategies to achieve the goal of ending the TB epidemic worldwide.

In Tuberculosis most of the infections that do not show any symptoms are called latent Tuberculosis. But only 10% of latent tuberculosis progresses into active

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APPENDIX XVIII

ACTION PICTURES

Picture-01: PTB Patient 1 performing Spirometry.

Picture-02: PTB Patient 2 performing Spirometry.

Picture-03: PTB Patient 3 performing Spirometry.

Picture-04: PTB Patient 4 practicing Meditation.

Picture-05: PTB Patient 5 practicing Pranayama.

Picture-05: PTB Patient 5 practicing Pranayama.

APPENDIX XIX

YOGA MODULE PRACTICE PHOTOS

I. BREATHING EXERCISES

1. Hands in and out breathing

2. Hands stretch breathing

3. Sasankasana breathing (moon pose)

II. LOOSENING EXERCISES:

4. Shoulder rotation

5. Forward and backward bending x 3 rounds

6. Instant Relaxation Technique

III. YOGASANAS/PHYSICAL POSTURES:

7. Ardhakati cakrasana (Lateral arc pose)

8. Ardha cakrasana (Half wheel pose)

9. Bhujangasana (Serpent pose)

10. Deep Relaxation Technique

IV. PRANAYAMA:

11. Nadisudhi Pranayama (Alternate nostril breathing)

12. Bhramari pranayama (Bee breathing)

V. RELAXATION:

13. Yoga Nidra (Guided Meditation)/Deep Relaxation Technique

9.3.2 Opportunities & Future Suggestions in the Yoga/ Integrative Medicine Research

1. Future studies can be planned with large sample sizes, multi-centric trials, different parameters for assessing, and different types of Yoga for patients with pulmonary TB.
2. It's essential to consider various factors like the patient's specific traits, family medical history, surroundings, and how long they've had the condition when creating exercise plans.
3. Customizing interventions based on individual physical and mental health needs, while paying attention to the intensity, frequency, and length of exercise, is crucial for achieving the best treatment results.
4. Working on the other psychological parameters such as Anxiety, stress, Psychosis, Feelings of loneliness and stress, Stigmatization and social isolation, and Economic hardships due to loss of income and medical expenses etc., can be studied in the future research.
5. Yoga research can be planned with Tuberculosis patients with the other Co-morbidities such as Diabetes Mellitus, HIV/AIDS, Cancers, respiratory diseases such as Asthma, COPD, COVID-19, cystic fibrosis, lung cancer, tuberculosis, bronchitis, and pneumonia can be studied.
6. Yoga research can be planned for extra-pulmonary tuberculosis focussing on the psychological problems.
7. Research in Yoga and tuberculosis can be planned for children below 18 years.

9.3.3 Challenges & Recommendations for Policy Makers:

- The policy makers should include the integrated Yoga as an adjuvant therapy to the standard of care in the future NTEP program for alleviating psychological problems, improving the pulmonary parameters and to enhance the quality of life So, the Yoga module may be included in future NTEP programs for better patient care.
- As already existing Yoga therapist at the Wellness centers at the Primary Healthcare centres (PHC's) can be trained in the module so that it enhances the adherence as well as improving the patient care and enhances the outcomes of NTEP programme.
- **Challenges:** Forming the policies to incorporate the Yoga in NTEP program and conduct more research with large sample size and multi-centric trails in the future.